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Chudy

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(54) **AUTOMATIC DRUG PACKAGING MACHINE AND PACKAGE-LESS VERIFICATION SYSTEM**

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G07F 17/00	(2006.01)
G06F 19/00	(2011.01)

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CPC ***B65B 5/103*** (2013.01); ***G07F 17/0092*** (2013.01); *G06F 19/3462* (2013.01)

(58) **Field of Classification Search**
CPC G07F 17/0092; G07F 11/62; G07F 9/026; G06F 19/3462; G06F 19/3456; B65B 5/103; B65B 57/00; G06Q 10/087; G06Q 50/22; A61J 7/0084; A61J 2205/30; A61J 2205/10; G01N 21/9508
USPC 53/53–54, 58, 494–495, 498–501, 507, 53/508; 382/141, 321; 700/244
See application file for complete search history.
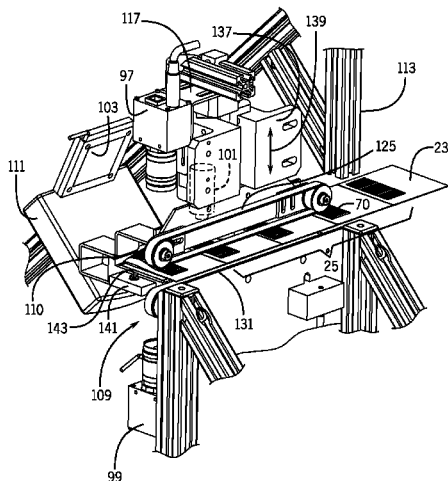
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(57) **ABSTRACT**

An automatic drug packaging machine and package-less verification system together with methods and apparatus. In embodiments, the system may include an automatic drug packaging machine for packaging one or more drug into ones of separate pouch packages forming a pouch package web. Each pouch package may include information, a machine-readable code, and have a side through which each packaged drug is viewable. An imager adjacent the web is provided to capture an image of each packaged drug within the pouch package. In embodiments, a code reader adjacent the web may read the pouch package machine-readable code. The code reader may be associated with the imager. In an embodiment, the machine-readable code is compared with an expected code for the pouch package and image information of each packaged drug within the pouch package is compared with a reference image corresponding to each packaged drug for a match. In such embodiment, data may be generated for the pouch package responsive to whether the codes match and whether the images match to provide a verification of the pouch package if the comparisons match and, alternatively, a non-verification of the pouch package if at least one of the comparisons do not match.

26 Claims, 27 Drawing Sheets

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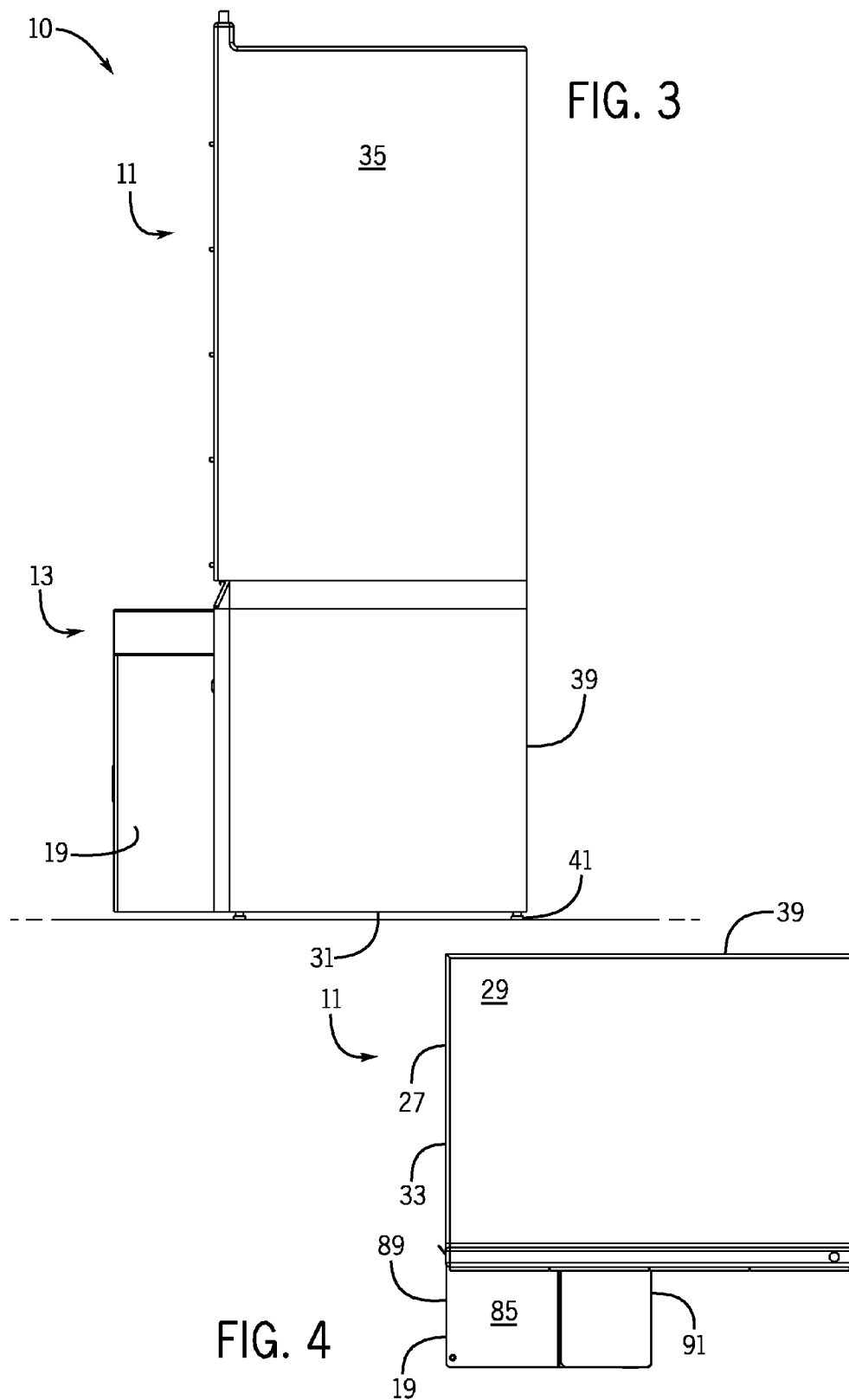|		
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FIG. 1

FIG. 2

FIG. 3

FIG. 4

FIG. 5

FIG. 6A

FIG. 6

TO VERIFICATION SYSTEM

FIG. 7

FIG. 8
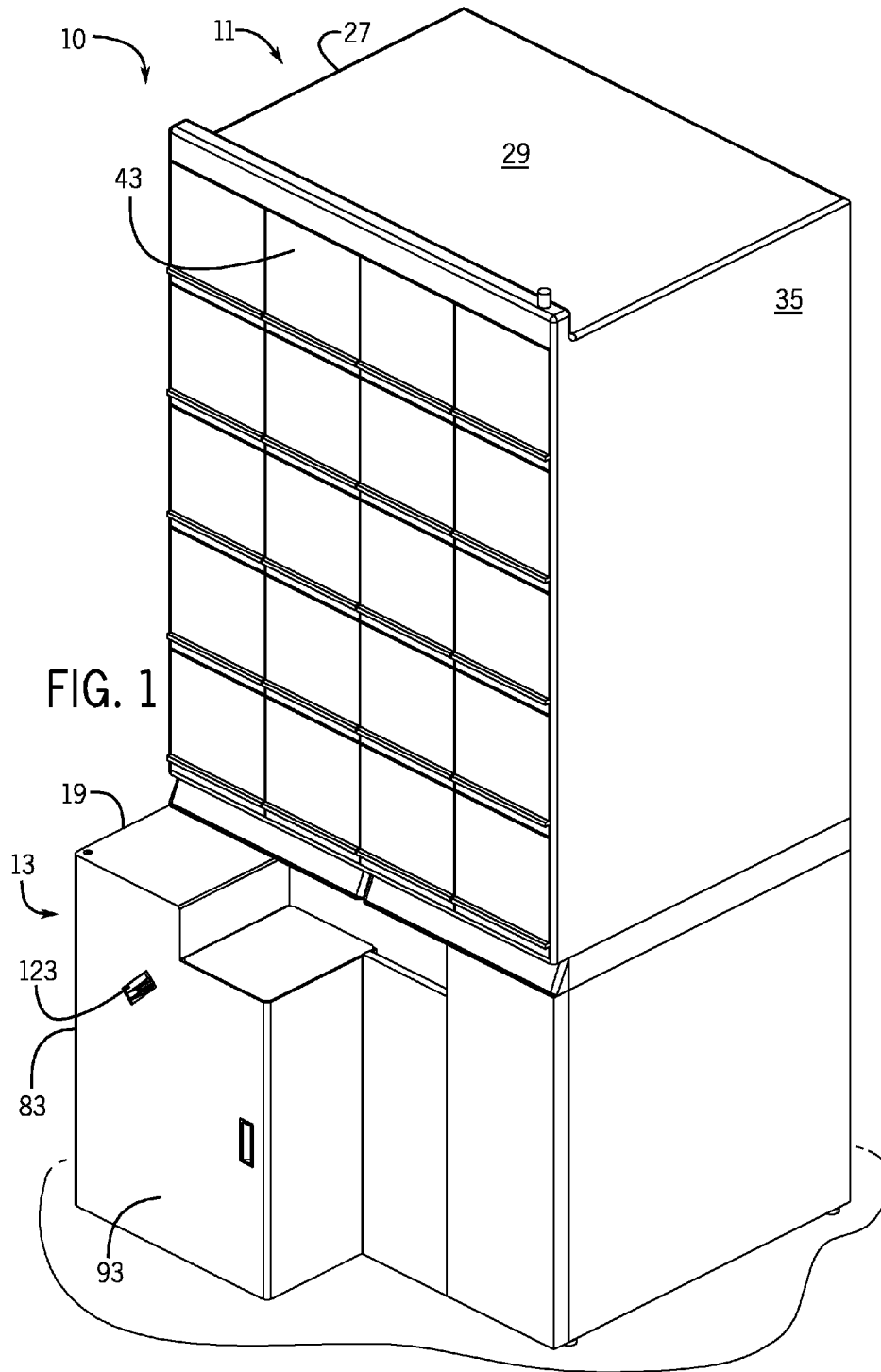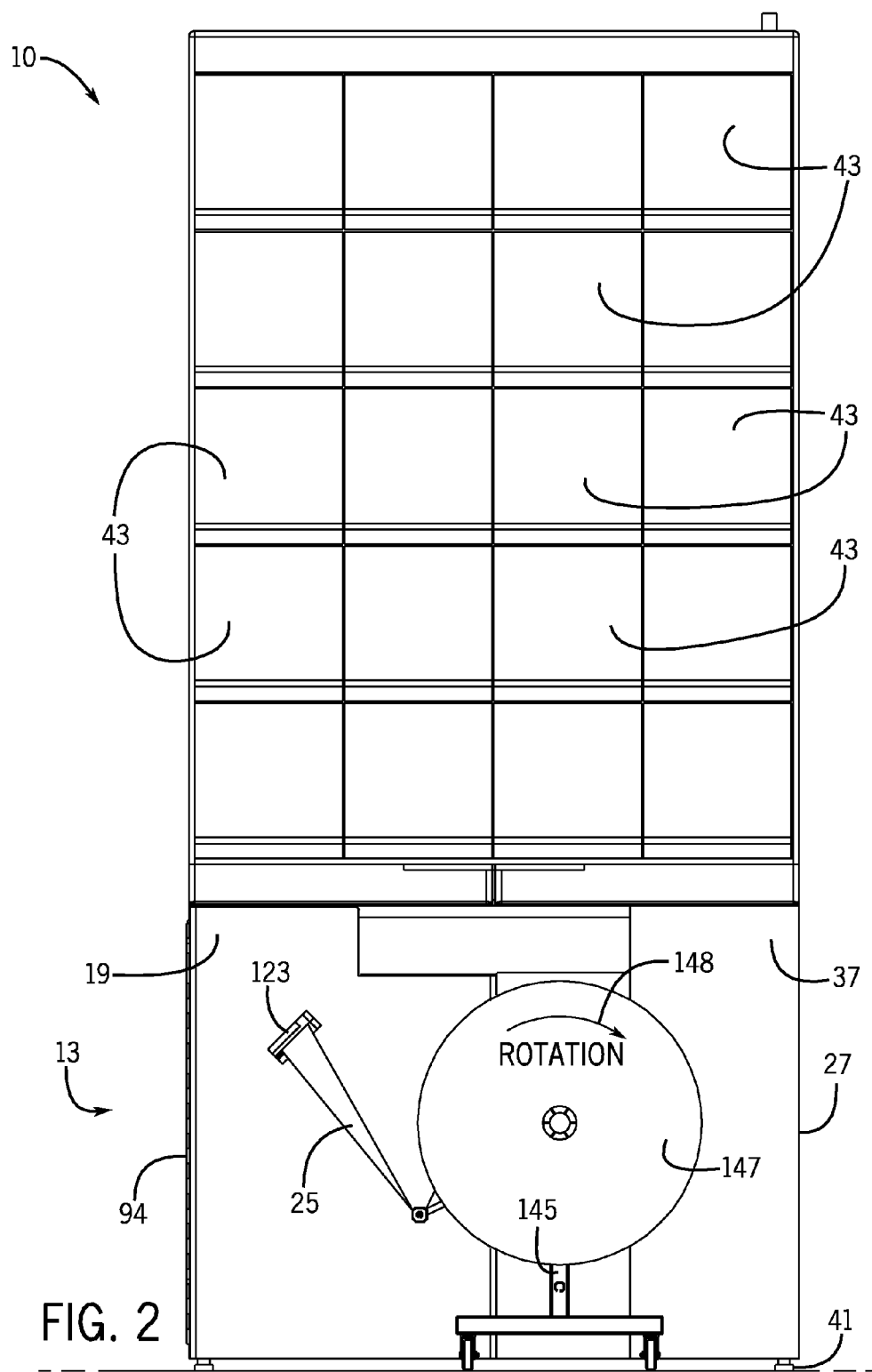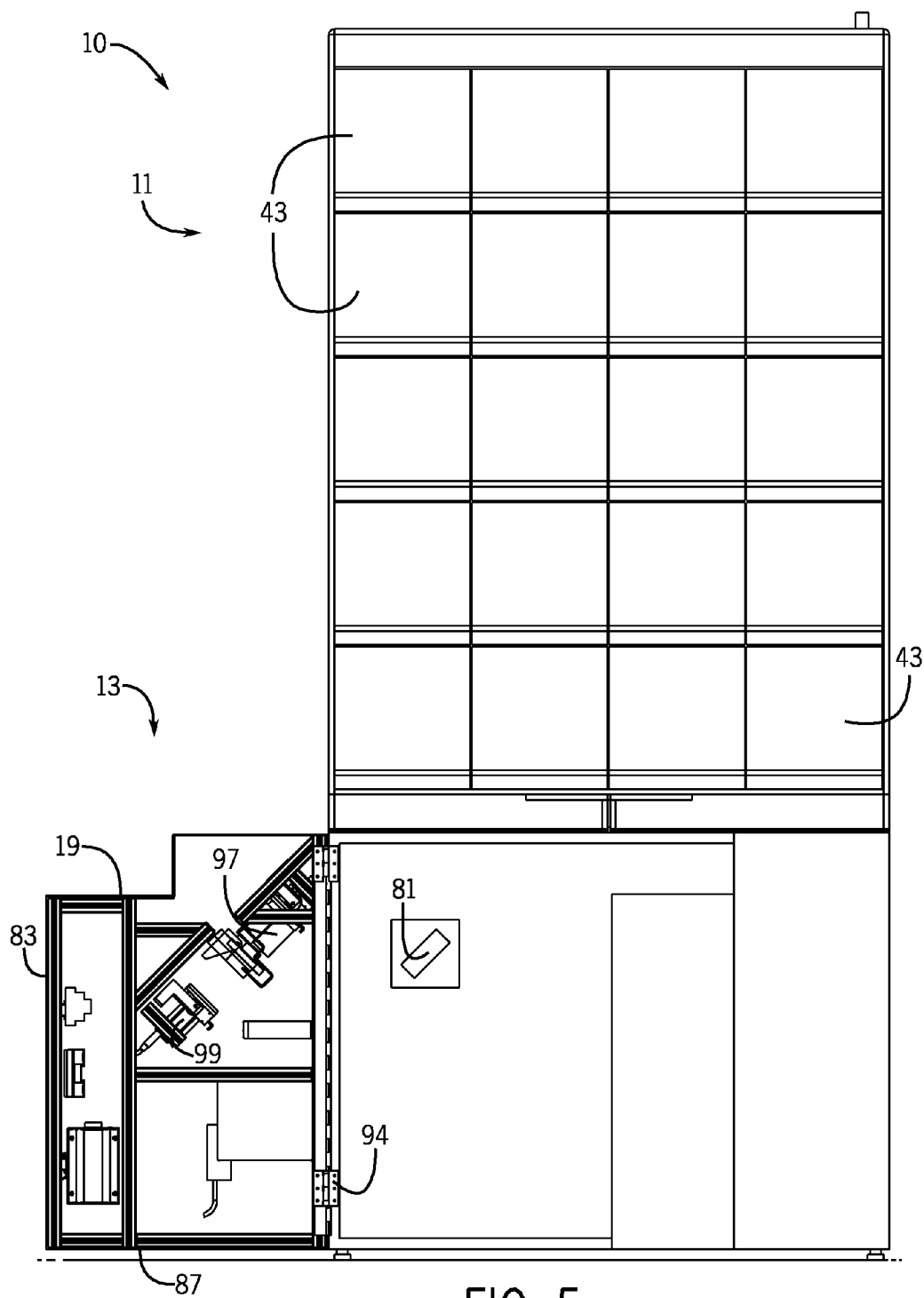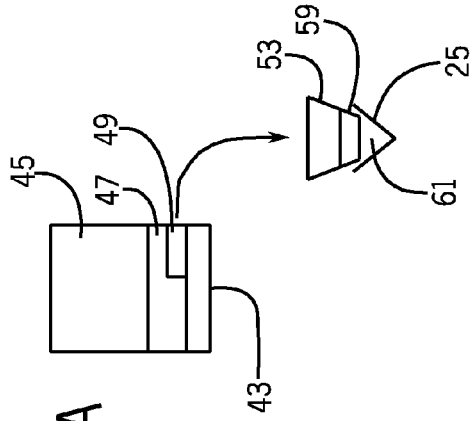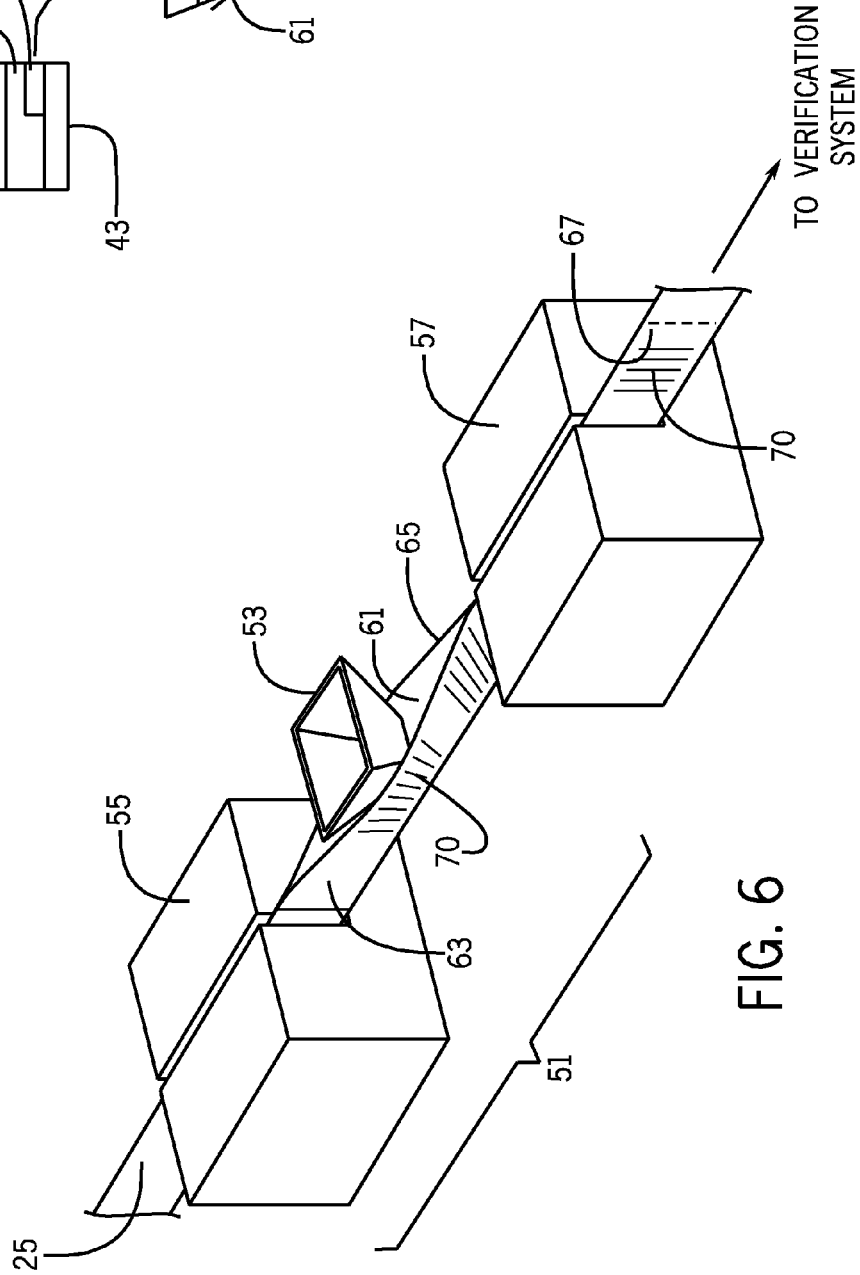
FIG. 9
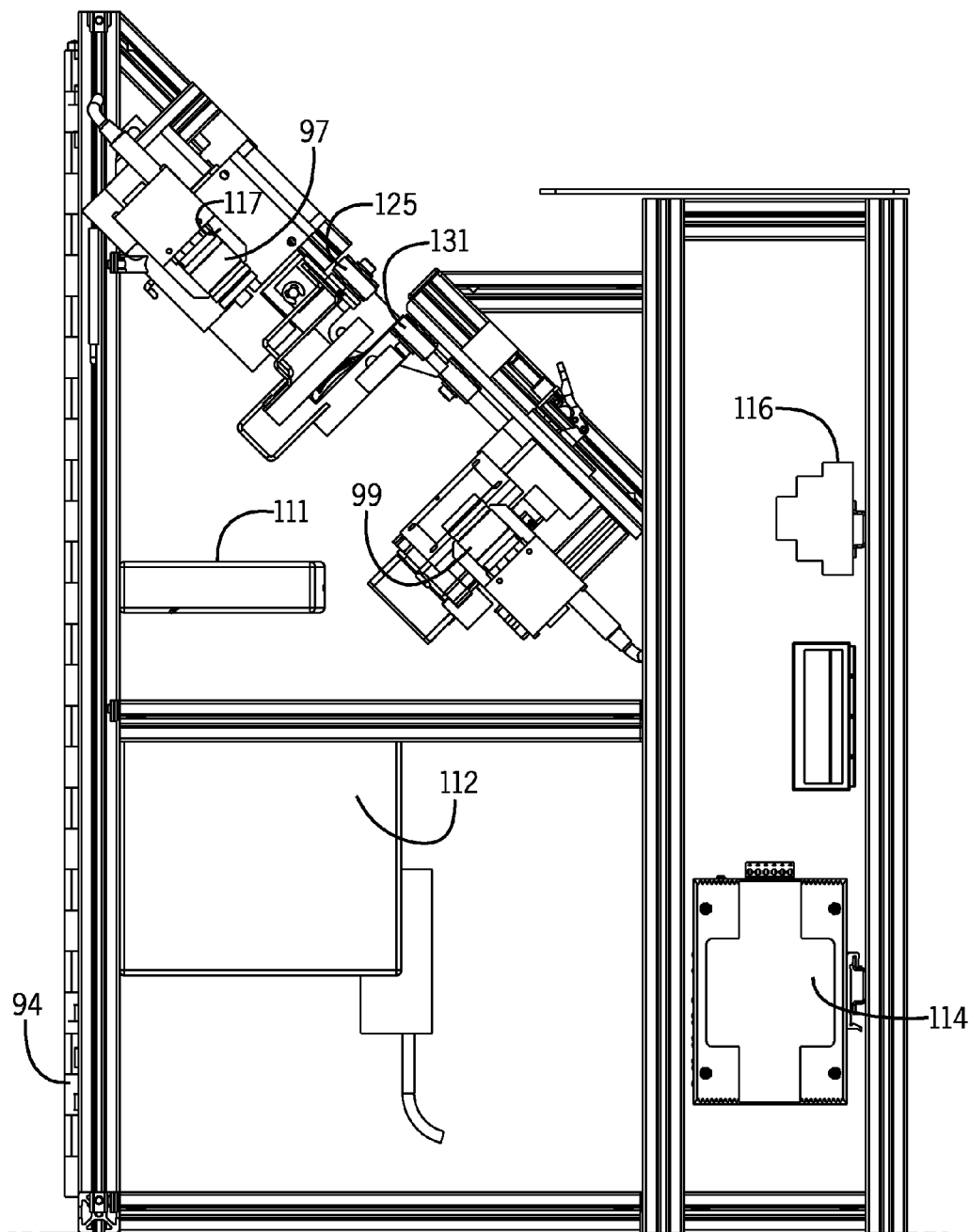
FIG. 10
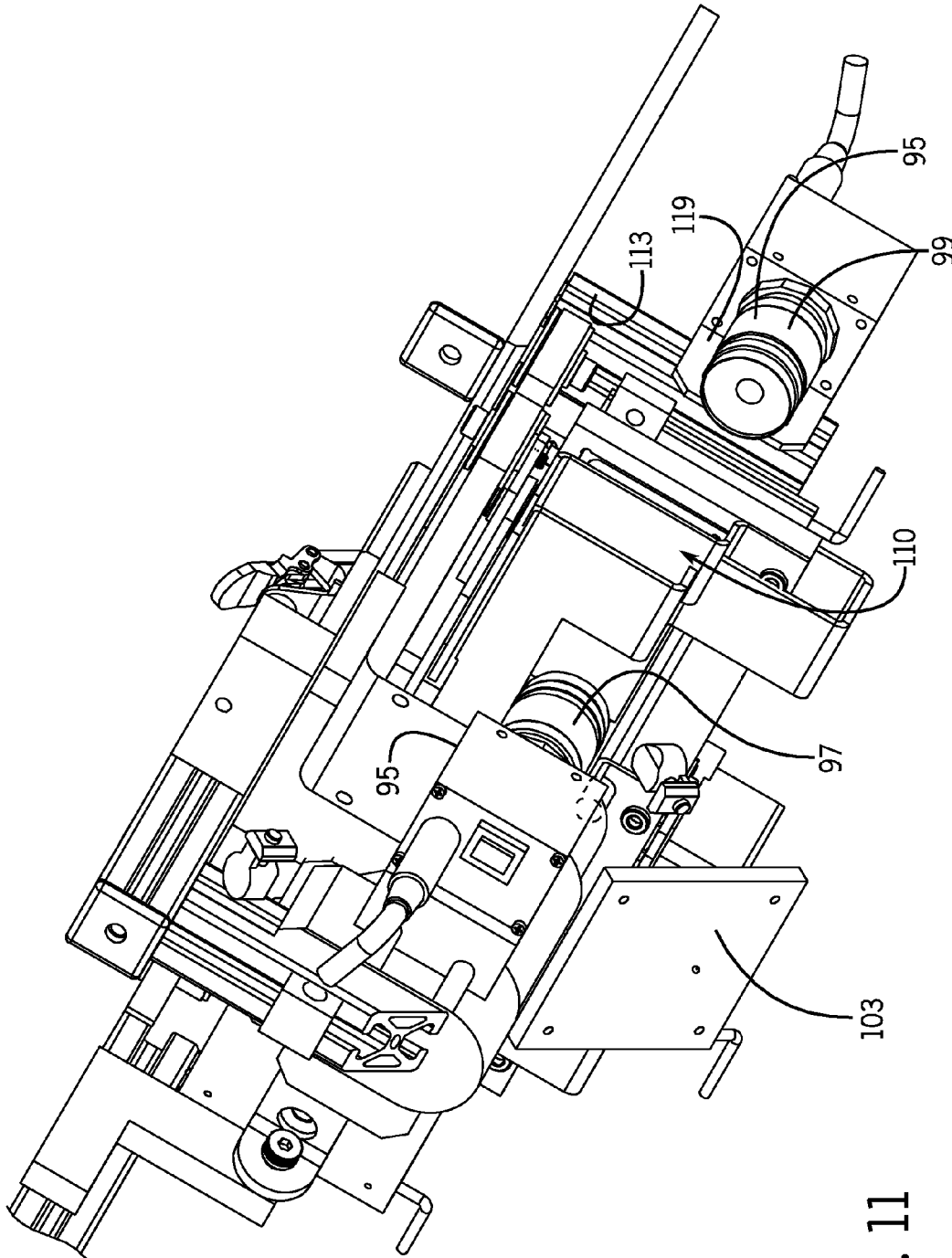
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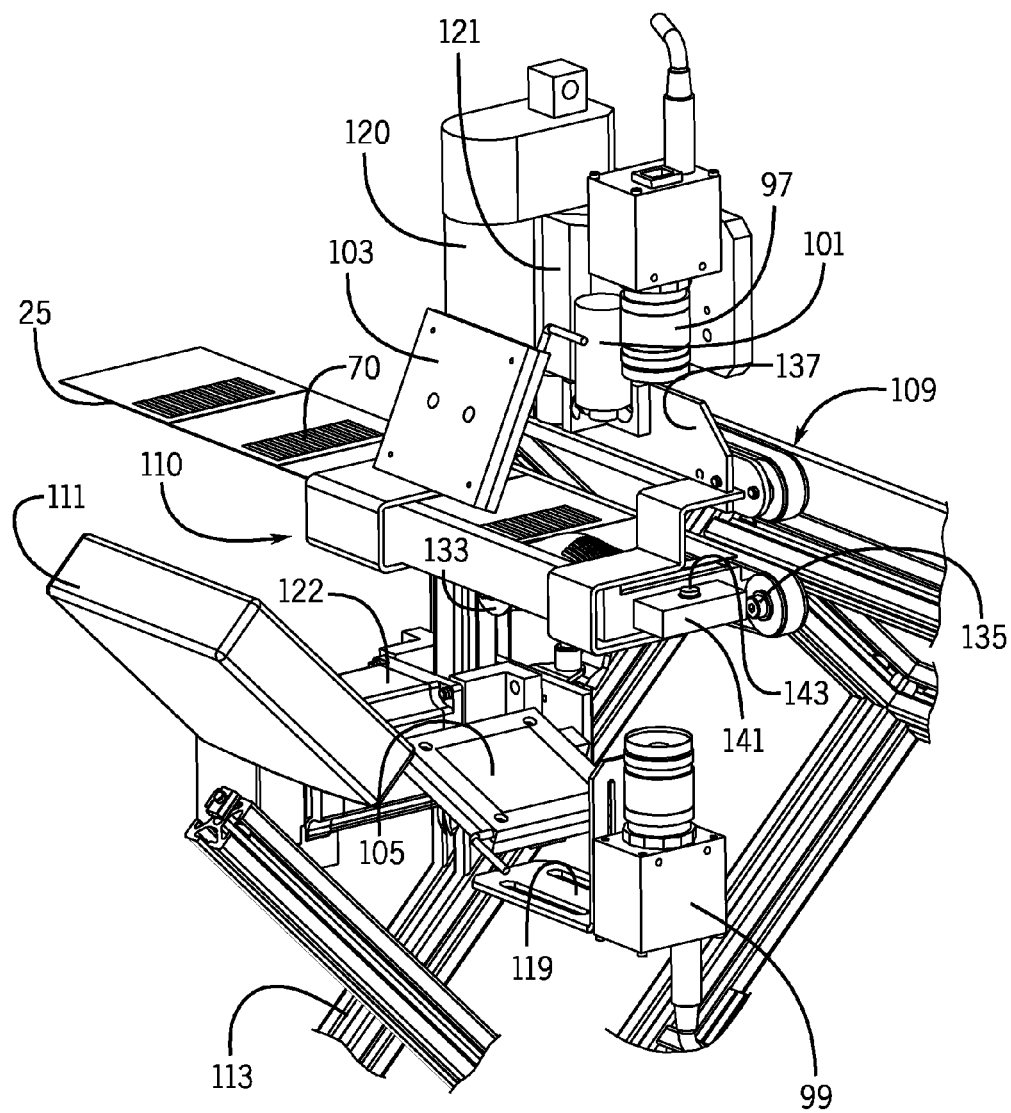
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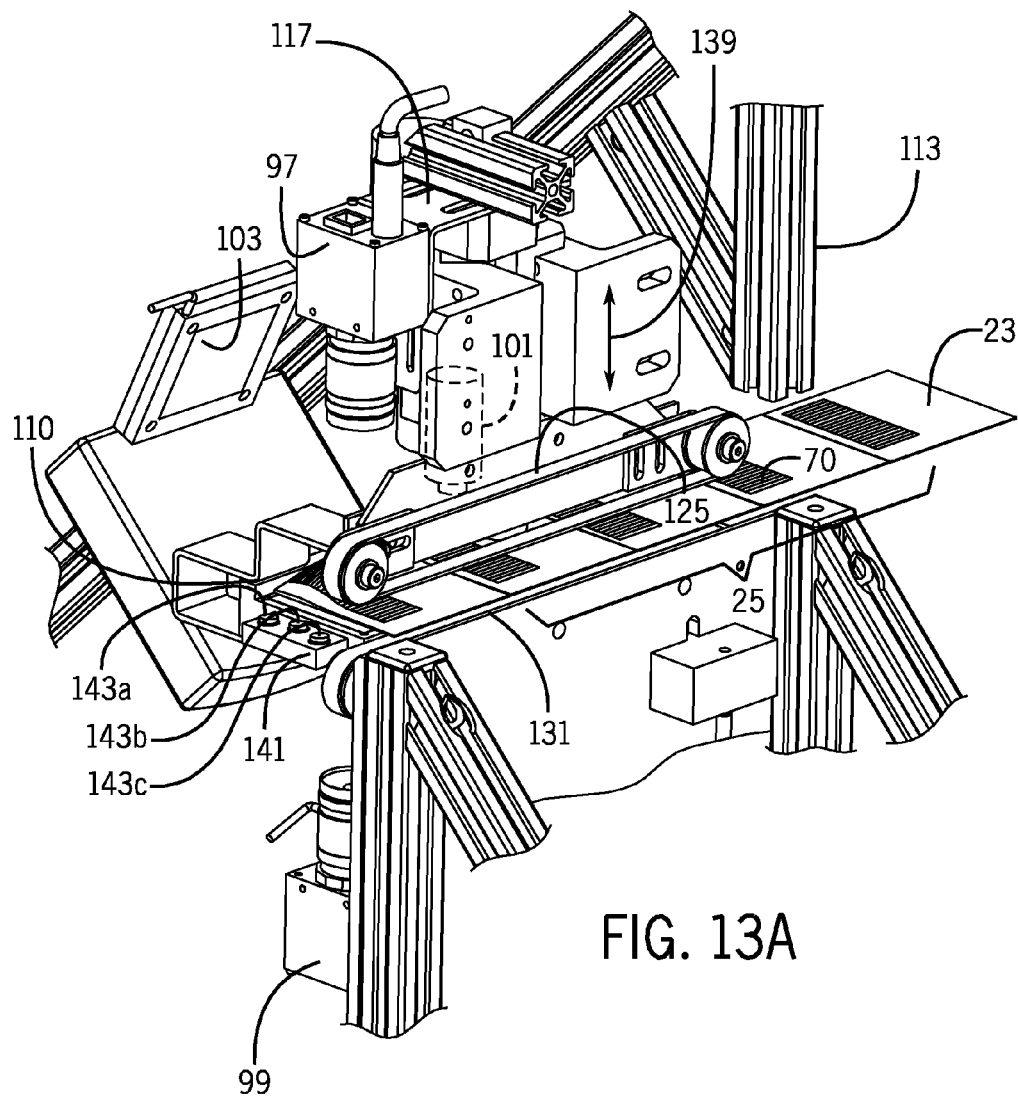
FIG. 13

FIG. 13A

FIG. 14

FIG. 15A

FIG. 15B

72
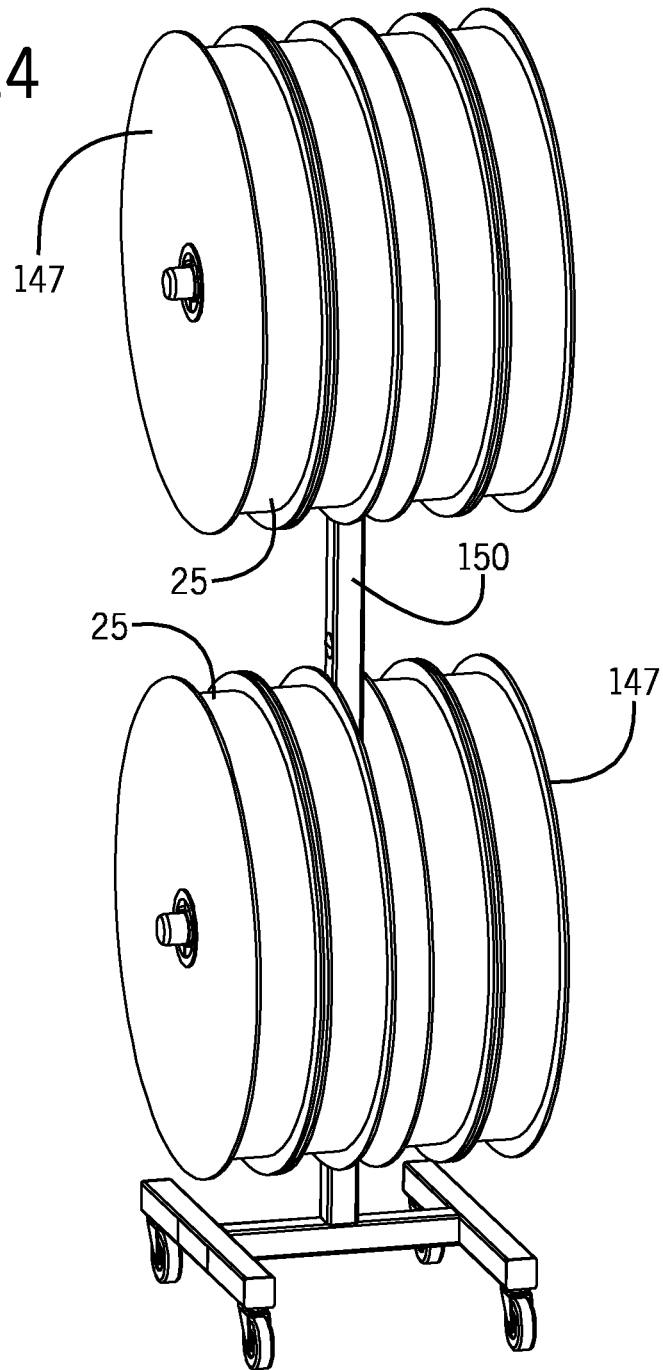
Date Packaged: 1-3-2011
Time Packaged: 8:00 AM

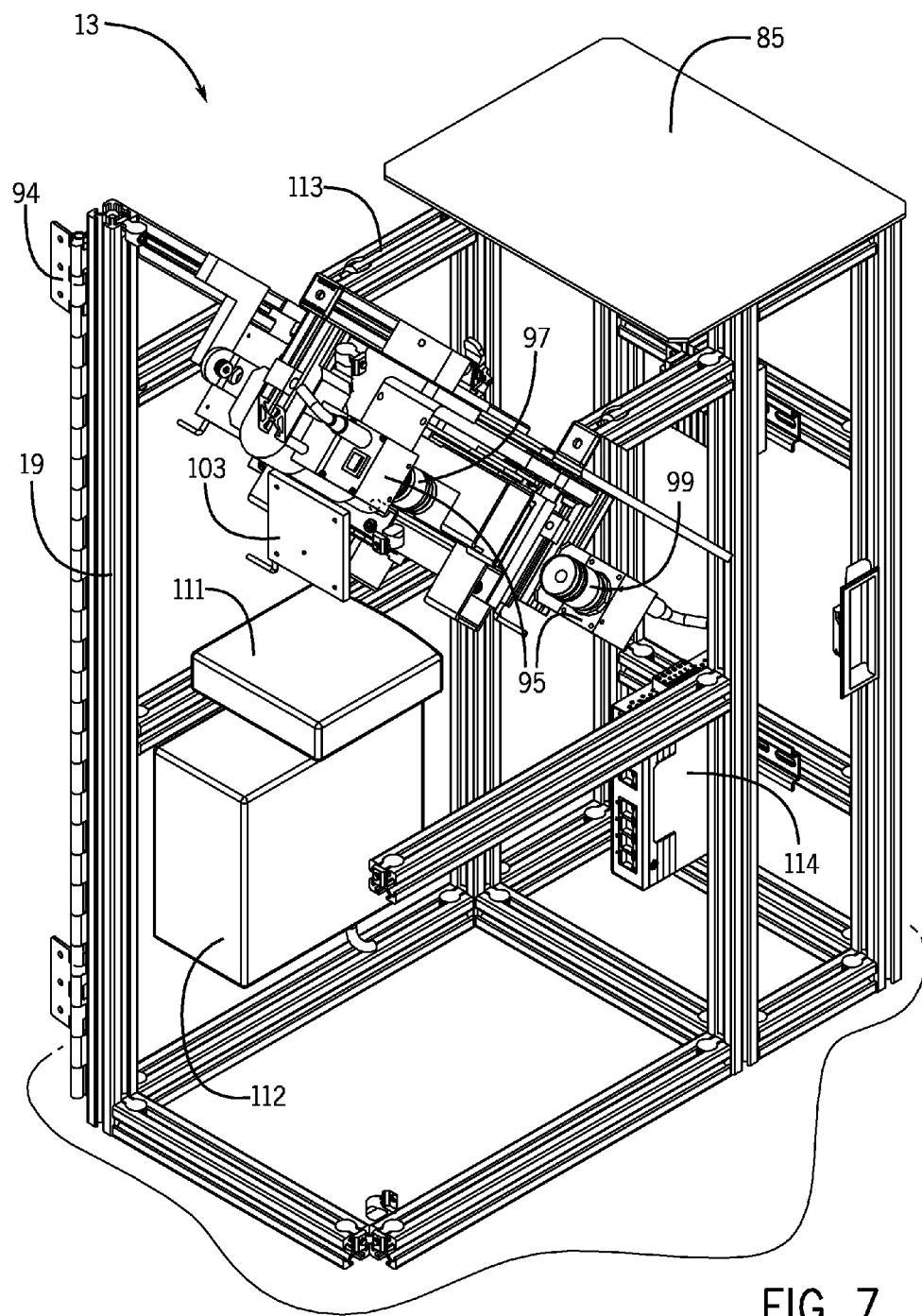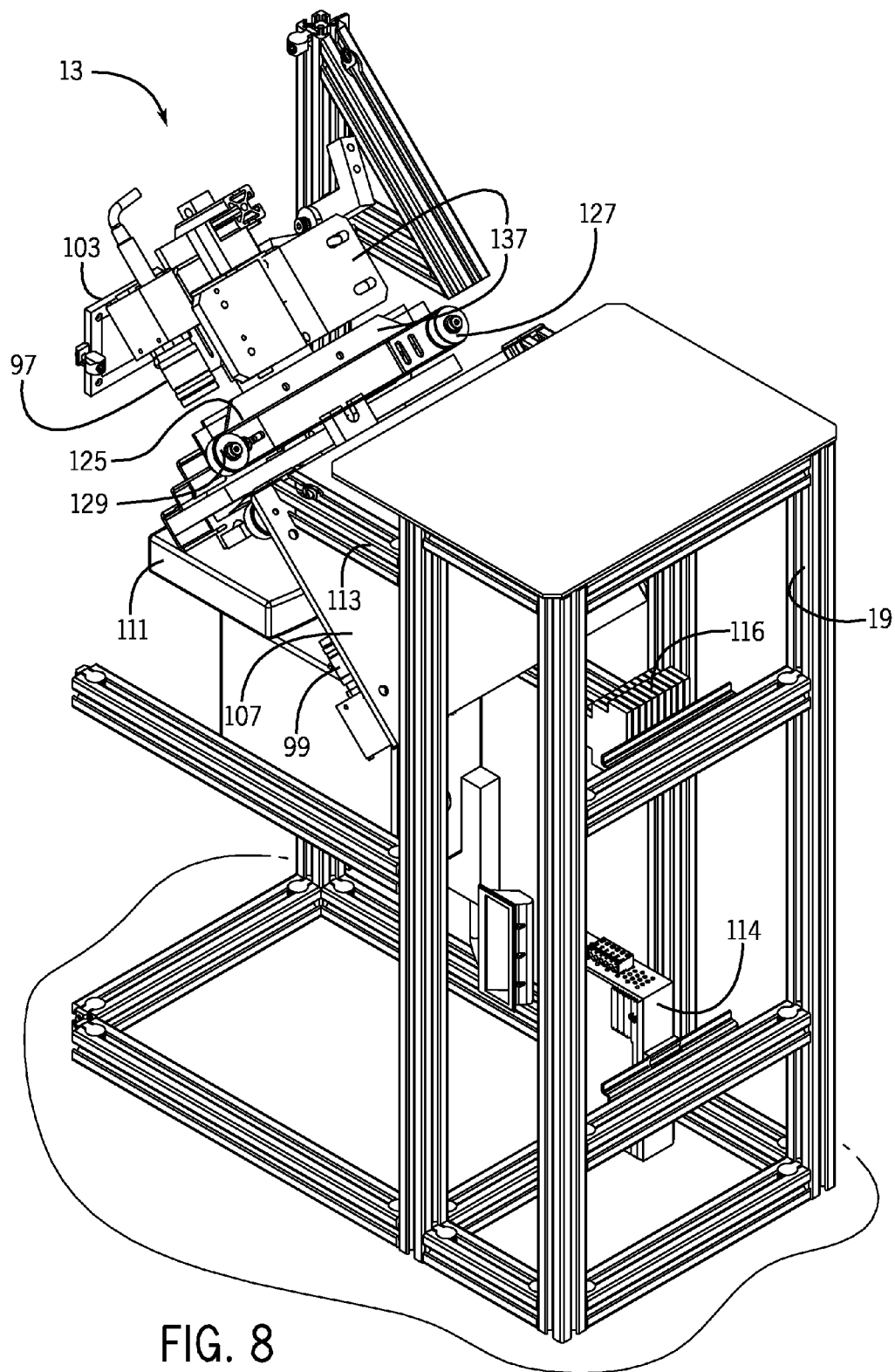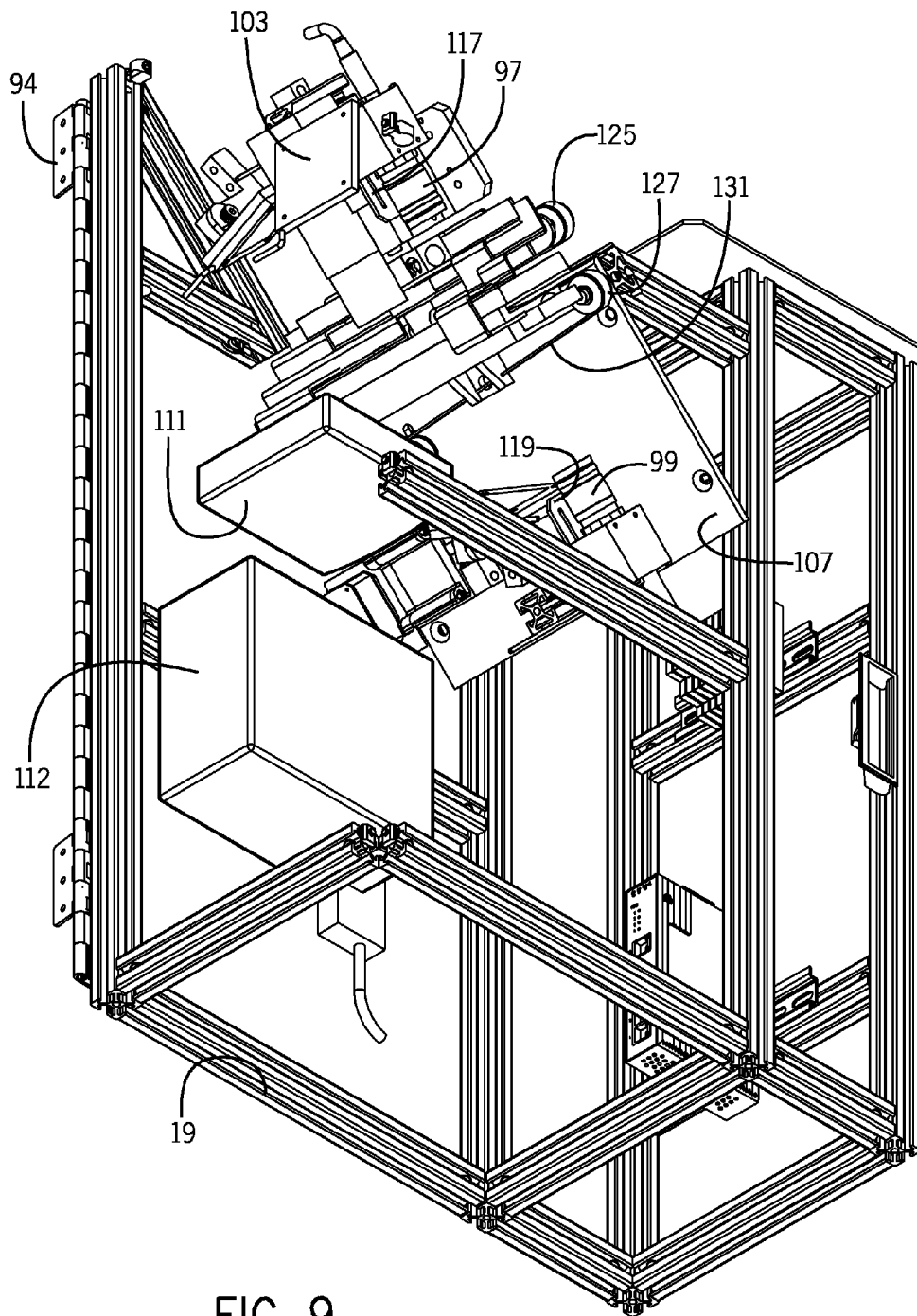Bag #:1 — 79

- -

*********START PATIENT*******
Doe, John
Patient ID: #1
Facilities: Demo Facilities
Room: E/202/-02
Dr. Test Sample

72

Date Packaged: 1-3-2011
Time Packaged: 8:00 AM

67

TCGRx Pharmacy
N1671 Powers Lake Rd.
Powers Lake, WI 53159
Ph: 555-262-5555

Bag #:2 — 79

70 71

- -

150

BREAKFAST
Doe, John
Take On: 1-3-2011 At: 9:00 AM
73

CYMBALTA 20MG
MFG: Duloxetine HCL
Desc: Grn/Obl/Cap/3225
Lot: 123
NDC:00002323560

ALPROZOLAMER 0.5MG
MFG: Duloxetine HCL
Desc: Wht/Rnd/Tb/21
Lot: 456
NDC:00378502191

75

23

CITALOPRAM 20MG
MFG: MYLAN
Desc: Obl/Wht
Lot: 789

67

Package Date: 1-3-12011   77
Time Packaged: 8:00 AM

Bag #:3

FIG. 16A   TO FIG. NEXT

FIG. 16B

FROM FIG. PREVIOUS

71

150

LUNCH
Doe, John
Take On: 1-3-2011 At: 12:00 PM

73

CYMBALTA 20MG
Duloxetine HCL
Desc: Grn/Obl/Cap/3225
Lot: 123
NDC:00002323560

23

75

CITALOPRAM   20MG
MFG: MYLAN
Desc: Obl/Wht
Lot: 789

67

Package Date: 1-3-2011
Time Packaged: 8:00 AM

77

|||||||||||||||||||||||| Bag #:4

79

70

71

150

DINNER
Doe, John
Take On: 1-3-2011 At: 6:00 PM

73

CYMBALTA 20MG
Duloxetine HCL
Desc: Grn/Obl/Cap/3225
Lot: 123
NDC:00002323560

23

75

CITALOPRAM   20MG
MFG: MYLAN
Desc: Obl/Wht
Lot: 789

67

Package Date: 1-3-2011
Time Packaged: 8:00 AM

77

|||||||||||||||||||||||| Bag #:5

79

Patients Last Bag:
Doe, John
Ph: 555-262-5555   Bag #:6

74

72

72

79

3225

69

21

21

23

TO FIG. NEXT

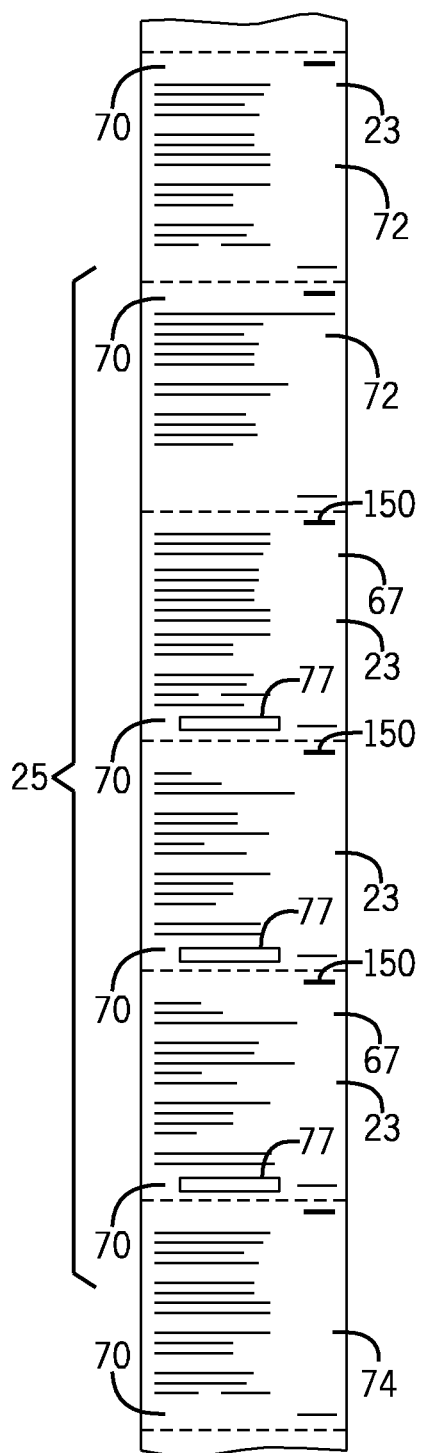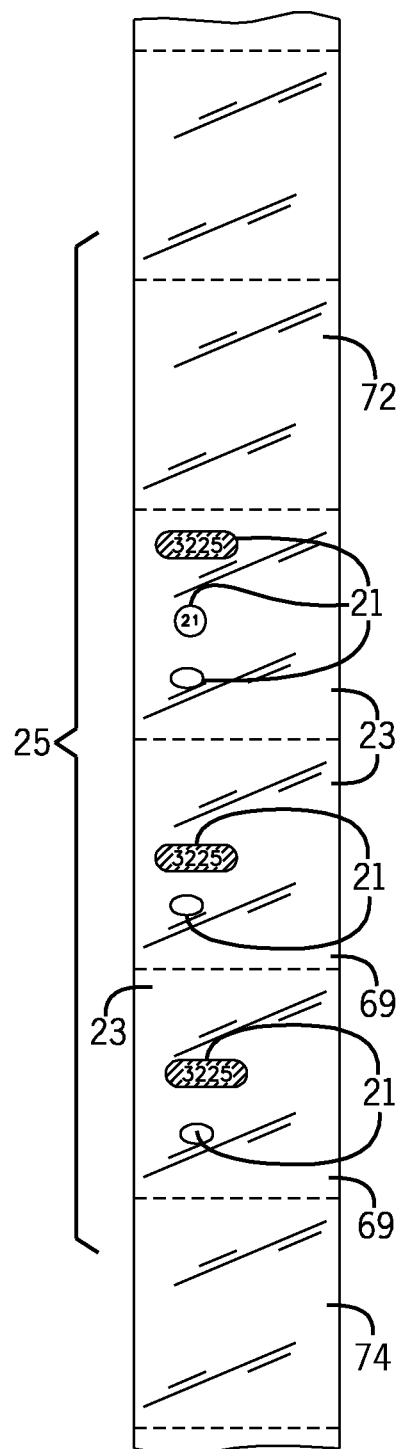FIG. 16C

FIG. 16D

FROM FIG. PREVIOUS

Date Packaged: 1-3-2011
Time Packaged: 8:00 AM

Bag #:1

— 72a

*********START PATIENT*******
Doe, John
Patie t ID: #1
Facilities: Demo Facilities
Room: E/202/-02
Dr. Test Sample

Date Packaged: 1-3-2011
Time Packaged: 8:00 AM

TCGRx Pharmacy
N1671 Powers Lake Rd.
Powers Lake, WI 53159
Ph: 555-262-5555

Bag #:2

— 69

25

— 79

— 150

BREAKFAST
Doe, John
Take On: 1-3-2011 At: 9:00 AM

— 23a

CYMBALTA 20MG
MFG: Duloxetine HCL
Desc: Grn/Obl/Cap/3225
Lot: 123
NDC:00002323560

3225

— 21

ALPROZOLAMER 0.5MG
MFG: Duloxetine HCL
Desc: Wht/Rnd/Tb/21
Lot: 456
NDC:00378502191

21

70

CITALOPRAM 20MG
MFG: MYLAN
Desc: Obl/Wht
Lot: 789

Package Date: 1-3-12011
Time Packaged: 8:00 AM

— 77

— 69

Bag #:3

FIG. 16E

DINNER
Doe, John
Take On: 1-3-2011 At: 6:00 PM

CYMBALTA 20MG
Duloxetine HCL
Desc: Grn/Obl/Cap/3225
Lot: 123
NDC:00002323560

CITALOPRAM   20MG
MFG: MYLAN
Desc: Obl/Wht
Lot: 789

ATTENTION:
Take Vital Signs Before
Administering Drugs

Bag #:5

— 76

— 79

25

— 150

DINNER
Doe, John
Take On: 1-3-2011 At: 6:00 PM

CYMBALTA 20MG
Duloxetine HCL
Desc: Grn/Obl/Cap/3225
Lot: 123
NDC:00002323560

CITALOPRAM   20MG
MFG: MYLAN
Desc: Obl/Wht
Lot: 789

Package Date: 1-3-2011
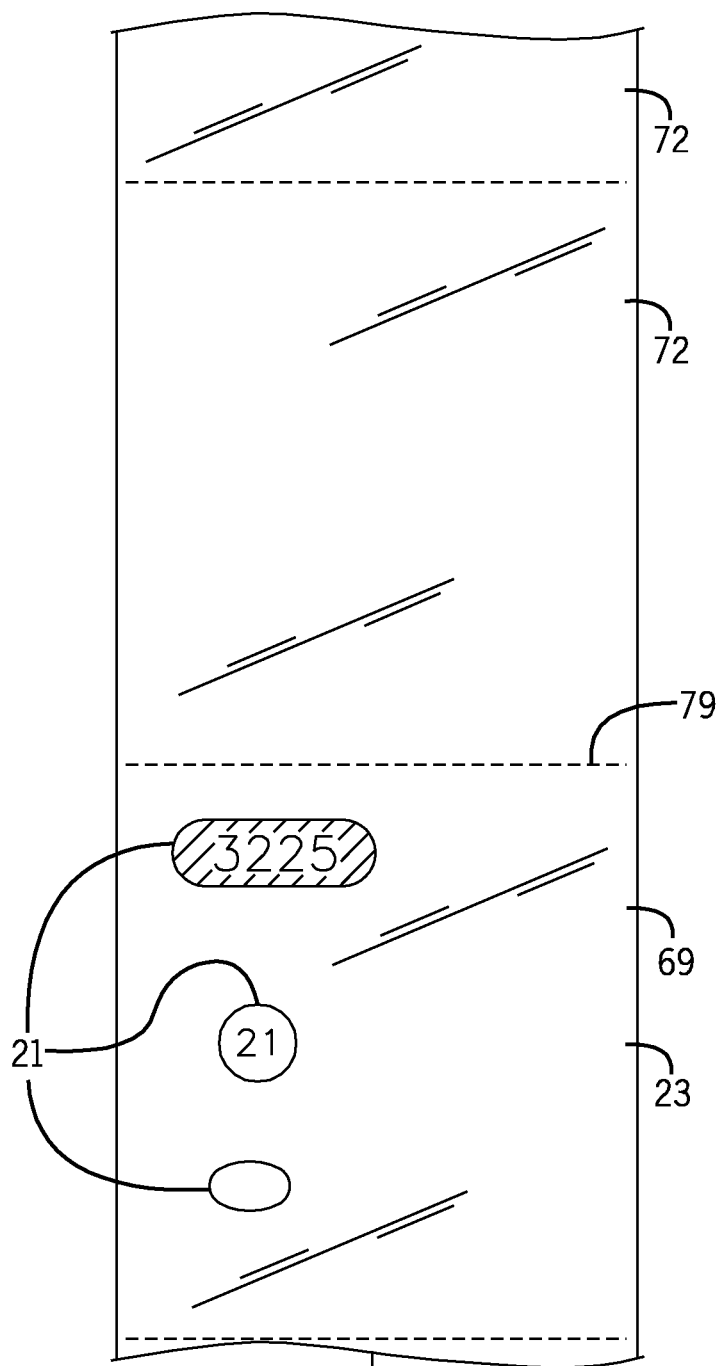Time Packaged: 8:00 AM
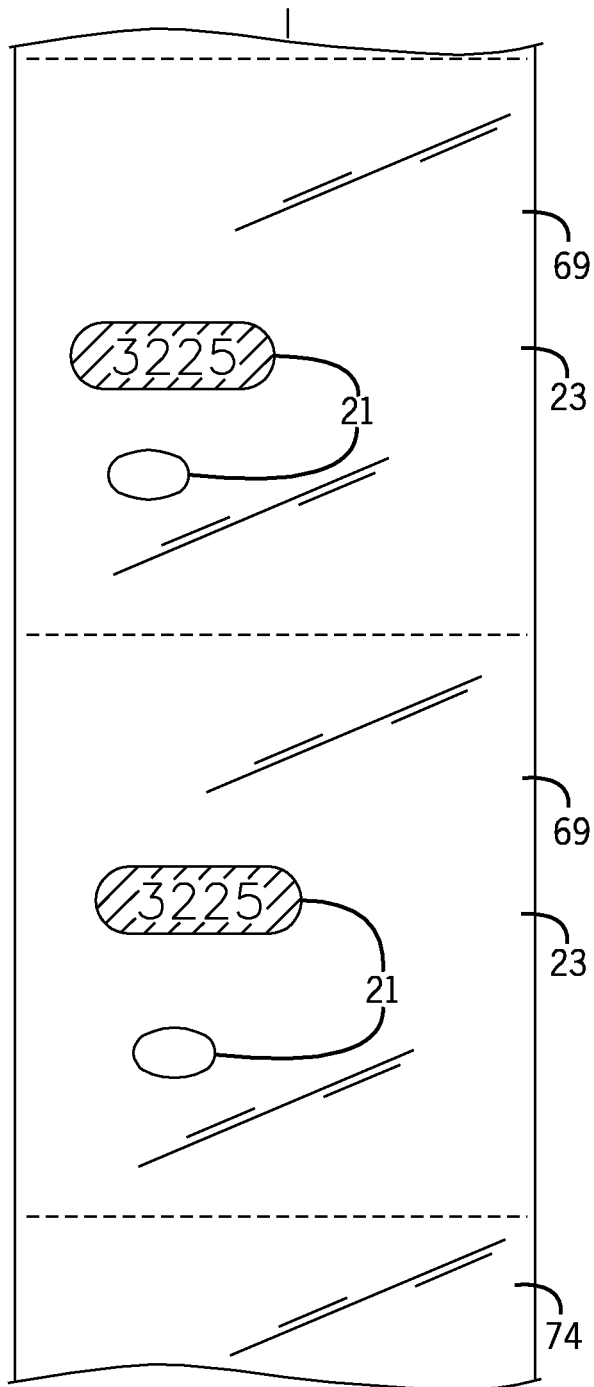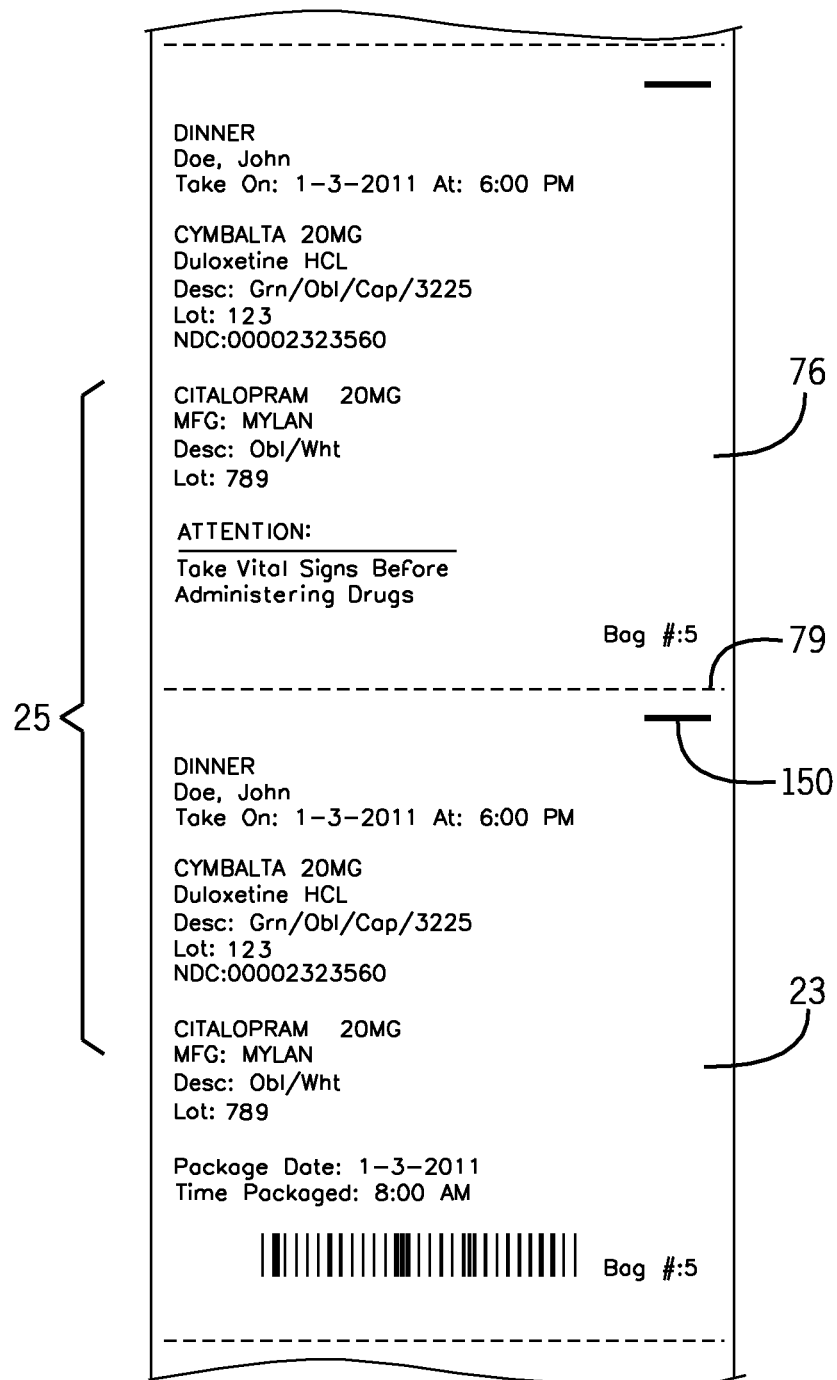
Bag #:5

23

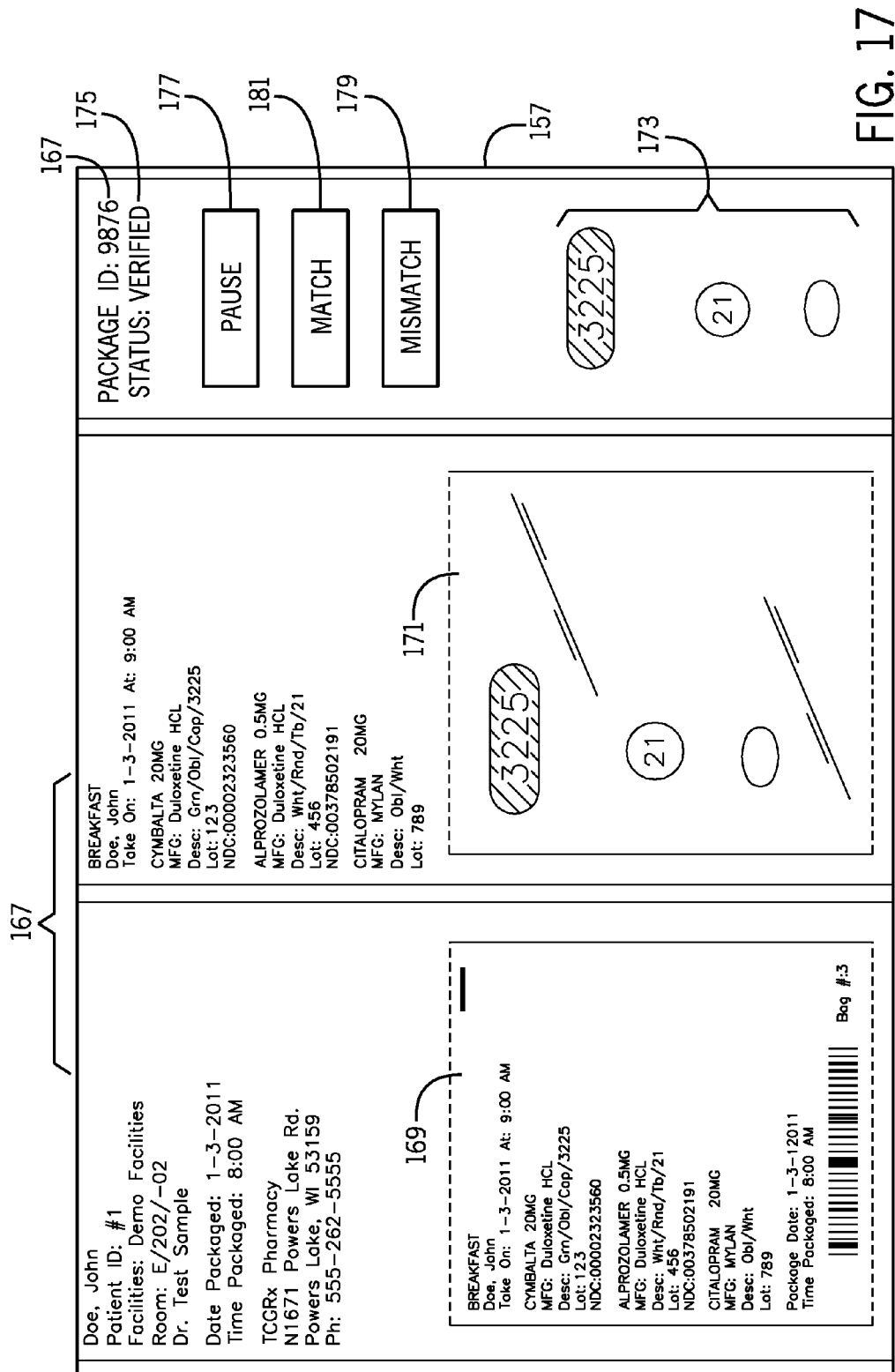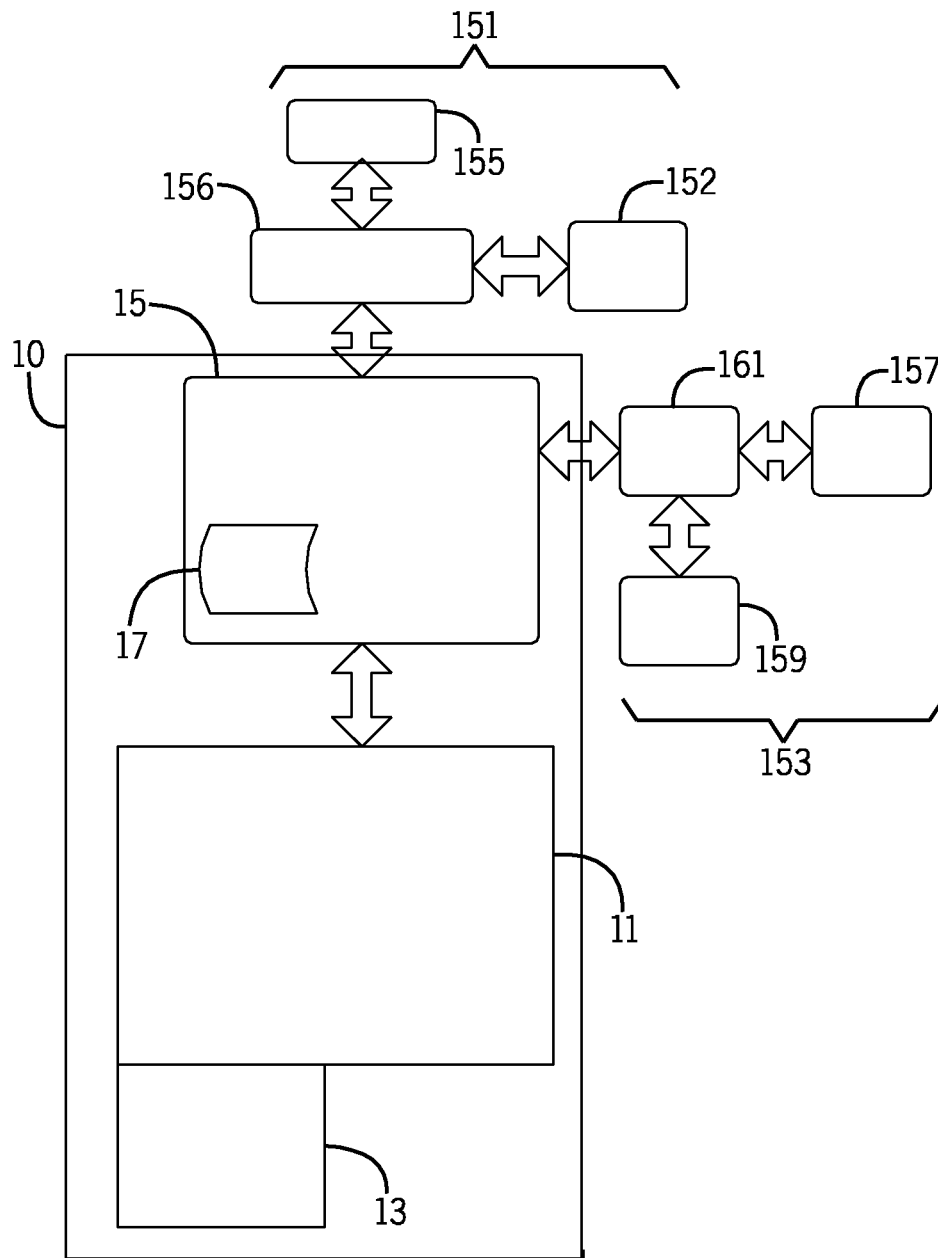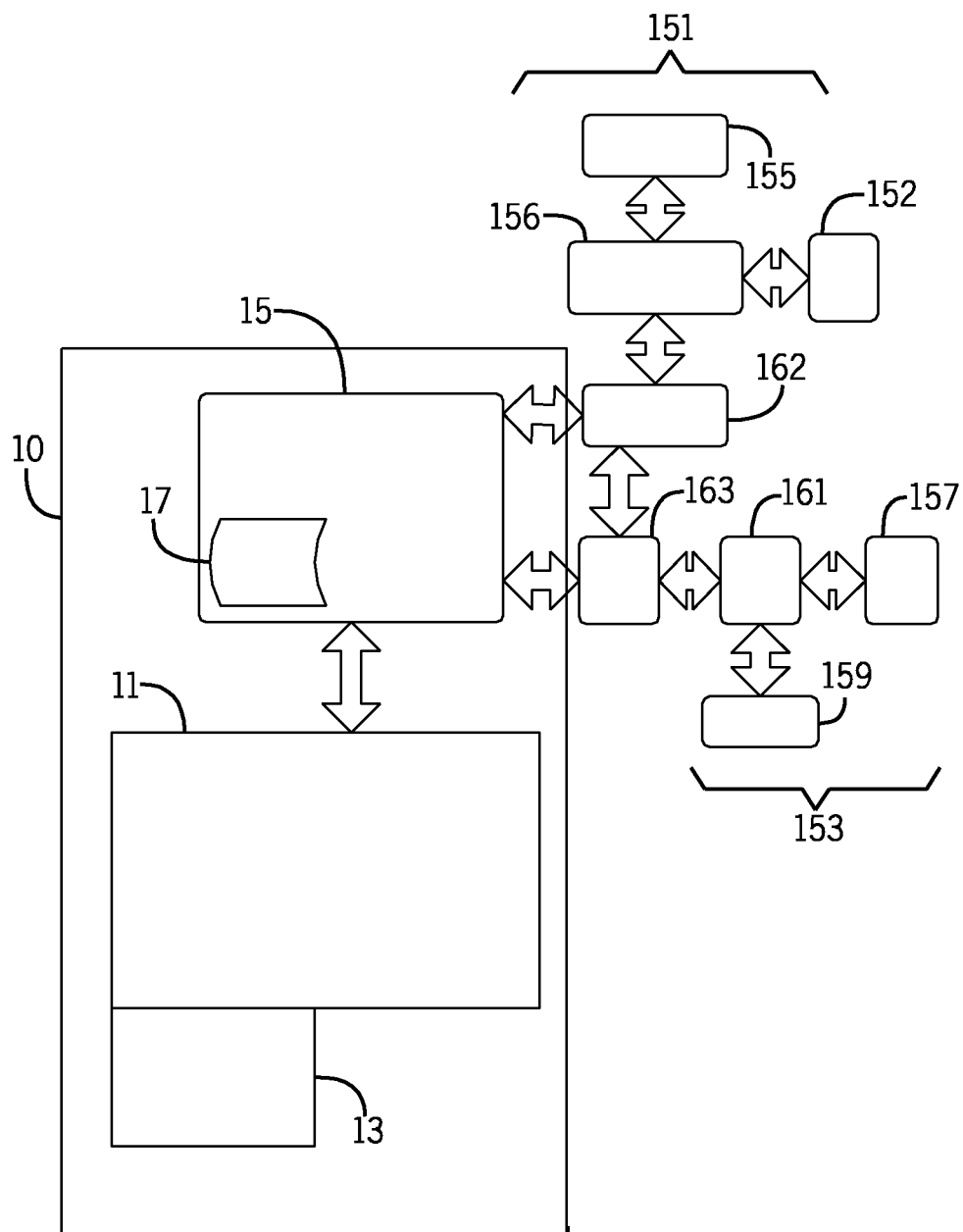FIG. 16F

FIG. 17

FIG. 18A

FIG. 18B

FIG. 19A

```
        ( Start )  —— 301

           │
  ┌─────────────────────┐
  │ Client creates Batch File │  —— 303
  └─────────────────────┘
           │
  ┌─────────────────────┐
  │ Client releases Batch │  —— 305
  │ File to ATP for real time │
  │ or delayed time mode │
  └─────────────────────┘
           │
  ┌─────────────────────┐
  │ ATP prints pouch, │
  │ machine readable code, │  —— 307
  │ registration mark and │
  │ then fills pouch based │
  │ upon batch file │
  │ information. │
  └─────────────────────┘
           │
  ┌─────────────────────┐
  │ Index to next pouch │  —— 309
  └─────────────────────┘
           │
        ◇ First pouch reached ◇  —— 311
        ◇ the vision module? ◇
           │ Yes
  ┌─────────────────────┐
  │ Camera with strobe │
  │ captures image of pouch │  —— 313
  │ content and printed text │
  │ triggered from │
  │ registration mark and │
  │ sends to PC/s │
  └─────────────────────┘
           │
  ┌─────────────────────┐
  │ Simultaneously bar code │  —— 315
  │ reader scans bar code/s │
  │ and sends data to PC/s. │
  └─────────────────────┘
           │
        ◇ Bar code data ◇  —— 317
        ◇ agrees w/Batch ◇ —No→
        ◇ File? ◇
           │ yes
        ◇ Real time ◇  —— 329
        ◇ Processing? ◇ —No→
           │ Yes   —— 331
  ┌─────────────────────┐
  │ Image of pouch content │
  │ displayed along side │
  │ corresponding drug image │
  │ standard and text based upon │
  │ batch file information for operator │
  │ visual match │
  └─────────────────────┘
           │
        ◇ Information ◇ —No→
        ◇ match? ◇
           │ Yes   —— 333
        ◇ Last file? ◇ —Yes→ [ Save log ] → ( End )
           —— 345      —— 351    —— 352
```

319 — Record mismatch and log occurrence

332 — Last file? —Yes→ Save Log —334→ End —336

320 — Real time processing? —No→
321 — Halt and resolve problem? —No→ Mark pouch for later retrieval and resume —326 Last file? —No→ (to Index to next pouch)
  Yes↓ 328 Save Log —330 End

323 — Stop and resolve problem
325 — Update log and resume

335 — Pause to confirm mismatch —No→ 339 Mark pouch for ID and log occurrence → 341 Halt and resolve problem
  Yes↓
337 — Mismatch confirmed? —No→   —Yes→

327

FIG. 19B

401
Start

403
Select batch file

405
Access first record

419
Next record

407
Verification error?

No ↓

Yes →

409
Image of pouch content displayed along side corresponding drug image standard and text based upon batch file information for operator visual image match.

411
Imformation match?

Yes →

No ↓

415
RPh record update log and resume

417
Last file?

No

Yes ↓

421
Save log

427
End

413
Resolve Problem

423
Image of pouch content displayed along side corresponding drug image standard and text based upon batch file information for operator visual image match.

425
Information match?

No →

Yes →

FIG. 20

Start — 501

Care giver at POC obtains pouch package — 503

Scan machine readable code on pouch package — 505

Call up file for pouch package — 507

Image of pouch content displayed along side corresponding drug image standard and text based upon batch file information for operator visual image match. — 509

Information match? — 511

No → Halt and resolve problem — 513

Yes

Scan patient bar code — 515

Patient bar code match batch file? — 517

No → Halt and resolve problem — 519

Yes

Accept and update log — 521

Administer drug — 523

End — 525

AUTOMATIC DRUG PACKAGING MACHINE AND PACKAGE-LESS VERIFICATION SYSTEM

FIELD

The field relates generally to automatic drug packaging and, more particularly, to systems for verification that the drugs are packaged correctly.

BACKGROUND

Prescription order fulfillment and administration of drugs to patients are important tasks which require the exercise of considerable care to ensure that the patient receives the correct drug in accordance with the physician's instructions. Because of the importance that prescription orders be fulfilled correctly, a registered pharmacist is required to review each prescription order and to verify that the prescription order has been fulfilled correctly. This prescription order review and verification process is performed before the prescription order is provided to the patient and before any drugs are administered to the patient to ensure that the patient receives the appropriate medical treatment.

Registered pharmacist prescription order review and verification is a time-consuming and relatively costly process. The registered pharmacist review and verification process can increase the cost of delivering high-quality patient care. The healthcare industry is under constant pressure to control these costs. Moreover, registered pharmacists are highly-skilled professionals whose time is valuable and can be spent, for example, performing other important tasks such as counseling patients.

Pharmacies are increasingly reliant on automation in order to improve the quality of patient care and to control healthcare costs. One highly-effective application of pharmacy automation is the use of automatic drug dispensing and packaging machines, referred to herein simply as automatic drug packaging machines. The automatic drug packaging machines may package the drugs in what are known as "compliance packages." Compliance packages organize the drugs in some useful manner to facilitate compliance with the physician's instructions.

One type of compliance package output by an automatic drug packaging machine is referred to in industry as a "pouch package." Pouch packages are formed serially in a web of pouch packaging material with each pouch package containing a drug "dose" consisting of one or more drugs. The drugs may be in tablet form or in other forms, such as granular or powdered form. The web of pouch packages output from the automatic drug packaging machine is sometimes referred to as a "vine." Each pouch package is a separate, sealed drug-containing package formed in the pouch package web, or vine. The pouch package web can be as long as required by the pharmacy or other automatic drug packaging machine operator. To facilitate compliance, the automatic drug packaging machine prints useful information on each pouch package, such as the patient name, drug information, and instructions for administration of the drug. The automatic drug packaging machine is computer controlled and may be programmed to output any number and sequence of pouch packages. An automatic drug packaging machine can operate for many hours, for example overnight, without human intervention.

Pouch packages are a useful type of compliance package because the packages may be output from the automatic drug packaging machine ordered in any suitable manner, such as

by the particular time of day at which the drug in each pouch is to be taken, (e.g., breakfast, lunch, and dinner). The pouch package web may be cut into smaller portions corresponding to each patient's prescription order and then may be provided to the patient. The patient then takes each drug one-after-the-other in the sequence in which the pouch packages are provided.

Pouch-package-type compliance packages are highly effective for drug administration at in-patient facilities, such as hospitals and long-term care facilities (e.g., nursing homes). This is because the pouch packages can be generated for many patients and can be grouped and organized in order of administration, thereby facilitating implementation of the physician's instructions and improving the quality of patient care.

While automatic drug packaging machines are excellent for their intended purpose, any automatic process carries with it the possibility of incorrect operation. For example, there may be a rare circumstance in which the wrong drug is packaged in the pouch package. There may be a rare circumstance in which a mismatch exists between a given pouch and the drug expected to be loaded in that pouch, potentially causing a series of drug and pouch package mismatches. There is also a limited possibility of printer error or malfunction so that the information printed on each package is not legible, or is unusable.

In these rare circumstances, pharmacy personnel must take corrective steps because the drugs cannot be administered unless the pharmacy is confident that the prescription order is correct and that any important printed information is usable. The corrective steps could involve discarding the pouch packages or expending valuable human time to manually remove the drugs from the pouch packages and to restock the drugs.

As valuable as automatic drug packaging machines are, the foregoing infrequent issues illustrate the importance of registered pharmacist prescription order review and verification before the pouch packages comprising a patient prescription order are administered to a patient. This review and verification is routinely performed by manually handling and checking each pouch package against printed or displayed information corresponding to the patient prescription order.

As can be appreciated, manual handling and review and verification of pouch packages is a slow and tedious process. Each pouch package web, or vine, may include many hundreds of look-alike pouch packages. The manual review and verification process is potentially subject to error because of the repetitive nature of the process and the look-alike appearance of the pouch packages. Therefore, while automatic drug packaging machines provide improvements in dispensing and packaging of the drugs, the prescription order fulfillment process is not optimally efficient because of the limitations imposed by the manual review and verification process of the pouch packages output from the automatic drug packaging machine.

Various inspection devices have been proposed to facilitate pouch package inspection. For example, U.S. Pat. No. 6,330, 351 describes a pouch package drug inspection device in which a camera-generated image of the actual pouch package content is compared with a reference image of the content. However, the drug inspection device is disadvantageous at least because it is incapable of detecting pouch package loading errors in real time as the pouch packages are output from the automatic tablet packaging machine.

A further pouch package inspection device is described in U.S. Pat. No. 7,540,222. This patent describes a manual inspection system in which a user manually examines an enlarged camera-generated image of each pouch package for

printing errors or for broken tablets. The inspection device is disadvantageous, however, at least because it is limited to manual detection of printing and tablet-damage errors and is not a prescription order verification system.

There is a need for an automatic drug packaging machine and package-less verification system which would address some or all of the foregoing needs, including needs of in-patient facility pharmacies and pharmacies generally, which would facilitate reliable and accurate prescription order review and verification, which would reduce the cost of pre-scription order review and verification, which would provide automatic "real time" detection of packaging errors thus avoiding creation of incorrectly-packaged pouch package webs, which would permit rapid and accurate verification of each pouch package without the need to physically handle any pouch package, and which would generally improve the quality of patient care.

SUMMARY

Exemplary systems, methods, and apparatus for an auto-mated drug packaging machine and package-less verification system are described herein. In an embodiment, there is pro-vided an automatic drug packaging machine and package-less verification system. In a preferred embodiment, an auto-matic drug packaging machine preferably includes a support structure and a packaging apparatus. In such embodiment, the packaging apparatus is provided to package one or more drug into ones of separate pouch packages. The pouch packages preferably form a pouch package web. In such preferred embodiment, each pouch package has associated informa-tion, a machine-readable code, and a side through which each packaged drug is viewable.

The preferred embodiment preferably includes an imager secured with respect to the support structure adjacent the web. The imager preferably captures an image of each packaged drug within the pouch package. The embodiment preferably further includes a code reader secured with respect to the support structure adjacent the web to read the pouch package machine-readable code. The preferred embodiment also pref-erably includes a computer programmed with instructions for performing a method of package-less verification of the pouch package.

In such preferred embodiment, the method implemented by the instructions comprises capturing an image of the pouch package side and each packaged drug viewable through the side, associating the image of the pouch package side and each packaged drug viewable through the side with a file for the pouch package, the file preferably including a code cor-responding to the machine-readable code, reading the pouch package machine-readable code with the code reader, and comparing the codes for a match. The method may further include comparing the image of the pouch package side and each packaged drug viewable through the side with a refer-ence image corresponding to each packaged drug for a match. The method may further include generating data for the pouch package responsive to whether the codes match and whether the images match, the data including at least a veri-fication of the pouch package if the comparisons match and, alternatively, a non-verification of the pouch package if at least one of the comparisons do not match.

Preferably, the generating of data for the pouch package responsive to whether the codes match occurs automatically after reading the pouch package machine-readable code, thereby providing the pharmacy or operator with an opportu-nity to immediately detect a pouch package error before a long, incorrect pouch package web is generated.

In embodiments, the automatic drug packaging machine further comprises a module. In an embodiment, the module preferably includes the support structure, and the imager and code reader are preferably secured to the support structure within the module. In embodiments, the module is capable of being secured to an automatic drug packaging machine hous-ing. In embodiments, the module may be a component sepa-rate from the automatic drug packaging machine. Preferably, the determination of whether the codes match implemented by the instructions occurs before the pouch package exits the module. Preferably, a record is created of the pouch package verification or non-verification. The record may be created in the file for the pouch package.

Various actions may be taken if the codes do not match. For example, an alarm may be generated or the process may be stopped if the codes do not match. By way of further example, a modification of the pouch package may be provided if the codes do not match to facilitate identification of the pouch package. In an embodiment, the modification may include an identification mark made on the pouch package.

In yet another embodiment, a classification code may be provided on the pouch package. For example, the pouch pack-age could be color coded to indicate the time of day that the drug is to be administered.

In another embodiment, a message package may be pro-vided in the pouch package web proximate the pouch pack-age. An exemplary message package may include informa-tion relating to the pouch package.

In other aspects, a pouch package may be provided in which the information associated with the pouch package is on the side through which each packaged drug is viewable and the information and each packaged drug are viewable simultaneously. In this embodiment, information and the appearance of the packaged drug could appear in a single captured image.

It is preferred that the machine-readable information of the pouch package is a barcode. The code reader may be a bar-code reader. In an embodiment, the imager may be the code reader. For example the imaging device may include the code reader as a component or capability.

In other aspects, the package-less verification system fur-ther comprises a display. The display may be utilized, for example, to compare: the image of the pouch package side, each packaged drug viewable through the side, and a refer-ence image corresponding to each packaged drug for a match. The display may be at a workstation.

In embodiments, the automatic drug packaging machine is at a first location and the display is at a second location spaced from the first location. This capability permits the package-less verification to be performed by a pharmacist in, for example, a city or state far from the automatic drug packaging machine without the necessity to have the pouch package physically present for verification.

In yet another embodiment, the imager may be configured to capture an image of information on a first side of the pouch package and to capture an image of each drug visible through the pouch package second side. In such an embodiment, the imager may comprise a first imaging device and a second imaging device. The first imaging device is preferably secured with respect to the support structure adjacent the web to capture an image of the information on the pouch package first side. The second imaging device is preferably secured with respect to the support structure adjacent the web to capture the image of the pouch package second side and each packaged drug viewable through the second side. Images of the first and second sides may be captured and the images of the pouch package first side and the pouch package second

side may be compared with a reference image during the verification process. The comparing may occur on a display.

In other embodiments, an image of the pouch package first side and an image of the pouch package second side may be associated with the file for the pouch package. It is further preferred that a record is created in the file that the pouch package has been verified as correct by a user, thereby creating an archive that the pouch package has been verified.

It is preferred that the system further comprises a printer and the computer programmed with instructions for performing a method further includes printing the information on a side of the pouch package. The printing may be on the side through which the drugs are visible, or an opposite side.

In yet another aspect, the printed information may include a registration mark detectable by the imager. Detection of the registration mark may be used to trigger capture of an image of a pouch package and reading of the pouch package machine-readable code. The information on the pouch package including the registration mark may be positioned on the pouch package based on a selected pouch package size so that the information is in an appropriate position for imaging by the imager.

Further exemplary systems, methods, and apparatus for an automated drug packaging machine and package-less verification system may be implemented in accordance with the principals described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Exemplary systems, methods, and apparatus for an automated drug packaging machine and package-less verification system may be understood by reference to the following description taken in conjunction with the accompanying drawings, in which like reference numerals identify like elements throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. The drawings depict only embodiments of the invention and are not therefore to be considered to be limiting of the scope of the invention. In the accompanying drawings:

FIG. **1** is a perspective view of an exemplary automatic drug packaging machine and package-less verification system;

FIG. **2** is a front elevation view of the exemplary automatic drug packaging machine and package-less verification system of FIG. **1**, together with a spooler for taking up a pouch package web output from the machine;

FIG. **3** is a side elevation view of the exemplary automatic drug packaging machine and package-less verification system of FIG. **1**;

FIG. **4** is a top plan view of the exemplary automatic drug packaging machine and package-less verification system of FIG. **1**;

FIG. **5** is a front elevation view of the exemplary automatic drug packaging machine and package-less verification system of FIG. **1** but with a pouch package verification system module swung away from the automatic drug packaging machine;

FIG. **6** is a schematic illustration of an exemplary packaging apparatus of the exemplary automatic drug packaging machine and package-less verification system of FIGS. **1-5**;

FIG. **6A** is a schematic illustration of exemplary cassette, motor base, hopper, and optional drug counter apparatus of the automatic drug packaging machine of FIGS. **1-5**;

FIG. **7** is a fragmentary left side perspective view of the exemplary pouch package verification system module of FIGS. **1-5**;

FIG. **8** is a fragmentary right side perspective view of the exemplary pouch package verification system module of FIGS. **1-5**;

FIG. **9** is a fragmentary bottom side perspective view of the exemplary pouch package verification system module of FIGS. **1-5**;

FIG. **10** is a fragmentary front elevation view of the exemplary pouch package verification system module of FIGS. **1-5**;

FIG. **11** is an enlarged fragmentary view of imaging devices, a web guide and other components of the exemplary pouch package verification system module of FIGS. **1-5**;

FIG. **12** is an enlarged fragmentary view of a code reader, an imager, a web guide and other components of the exemplary pouch package verification system module of FIGS. **1-5**;

FIG. **13** is an enlarged fragmentary view of a code reader, an imager, a web guide and other components of the exemplary pouch package verification system module of FIGS. **1-5**;

FIG. **13A** is an enlarged fragmentary view of an alternative marking device embodiment and other components capable of use with the exemplary pouch package verification system module of FIGS. **1-5**;

FIG. **14** is a perspective view of an exemplary storage and moving rack, shown loaded with plural spools containing packaged pouch package web;

FIG. **15A** is a top plan view of a first side of a portion of an exemplary pouch package web of a type output from the automatic drug packaging machine of FIGS. **1-5**;

FIG. **15B** is a top plan view of a second side of the portion of an exemplary pouch package web of FIG. **15A**;

FIGS. **16A** and **16B** are enlarged views of portions of the exemplary pouch package web of FIG. **15A**;

FIGS. **16C** and **16D** are enlarged views of portions of the exemplary pouch package web of FIG. **15B**;

FIG. **16E** is an enlarged view of a pouch package embodiment in which information is provided on a transparent side enabling simultaneous viewing of the information and drug;

FIG. **16F** is an enlarged view of a pouch package embodiment including a message package;

FIG. **17** is an exemplary verification workstation video display for a pouch package during verification;

FIGS. **18A** and **18B** are block diagrams illustrating exemplary automatic drug packaging machine and package-less verification system embodiments;

FIG. **19A** is a flow diagram showing exemplary methods of real time package-less verification;

FIG. **19B** is a flow diagram showing exemplary methods of delayed time package-less verification; and

FIG. **20** is a flow diagram showing an exemplary method of point of care verification.

DETAILED DESCRIPTION

An exemplary automatic drug packaging machine and package-less verification system **10** will first be described with respect to FIGS. **1-13A**. As used herein, "package-less" means or refers to having the capability to verify that the patient prescription order is correct without the necessity to physically handle or touch the drug or drug container during the verification process. The exemplary automatic drug packaging machine and package-less verification system **10** provides for improved error detection during the prescription order fulfillment process, both in terms of providing improved confidence that the prescription order is correct and in decreasing the time required to verify that the prescription

order is correct. As a result, demands on the registered pharmacist and pharmacy personnel generally are decreased, health care costs are controlled, and the quality of patient care is improved.

It should be understood that several preferred embodiments of the present invention are described herein and they are thus representative of the subject matter which is broadly contemplated by the present invention. The scope of the present invention fully encompasses other embodiments and equivalents. Furthermore, the described features, advantages, and characteristics of the invention may be combined in any suitable manner in one or more embodiments. One skilled in the relevant art will recognize that the invention may be practiced without one or more of the specific features or advantages of a particular embodiment. In other instances, additional features and advantages may be recognized in certain embodiments that may not be present in all embodiments of the invention. Features and advantages of the present invention will become more fully apparent from the following description and appended claims.

Automatic Drug Packaging Machine and Package-Less Verification System

Referring then to FIGS. **1-13A**, the exemplary automatic drug packaging machine and package-less verification system **10** comprises an automatic drug packaging machine **11** and a package-less verification system **13**. Exemplary system **10** further comprises a computer **15** with a central processing unit ("CPU") and associated non-volatile memory **17**. Computer **15** is programmed with a set of instructions, which may be in non-volatile memory **17**, for execution by system **10**. Computer **15** may, for example, consist of a main frame, a server, an off-the-shelf personal computer ("PC"), or plural operably-connected servers or PCs. One of ordinary skill in the art will appreciate that computer **15** can be dedicated to system **10** or can be a computer which is shared by multiple modules, including a pharmacy information system which controls the overall operation of a pharmacy operating the system.

In an embodiment, verification system **13** may be integrated with the automatic drug packaging machine **11**. In a further embodiment, such as the example of FIGS. **1-13**, the verification system **13** may be provided in the form of a modular component **19** added to the automatic drug packaging machine **11**. It is expressly contemplated that such a modular component **19**, including some or all portions of the package-less verification system **13**, may be provided as a component separate and apart from the automatic drug packaging machine **11**. This latter arrangement permits an automatic drug packaging machine **11** to be retrofit and upgraded with a package-less verification system **13**. Moreover, module **19** is exemplary only. It is further expressly contemplated that the package-less verification system **13** may be provided in a form other than module **19**.

In the example and as illustrated in FIGS. **2, 6, 12-14**, and **15A-16F**, the automatic drug packaging machine **11** dispenses and packages one or more drug **21** in individual ones of separate pouch packages **23**. In other words, one or more drug **21** is contained in each pouch package **23**. As used herein, "drug" includes any medicament and chemical substance used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being, and can include nutriceuticals such as vitamins and supplements. Each pouch package **23** is formed serially in a pouch package web **25**, also referred to herein as a web or a vine.

The pouch packages **23** may be provided as compliance packages to facilitate patient compliance with the physician's instructions as set forth in a prescription. To this end, a vine may be organized and arranged so that each pouch package **23** and drug **21** in each pouch package **23** are in the order in which each drug **21** is to be taken. Each pouch package **23** may be organized in any other manner desired by the pharmacy or other operator. For example, all pouch packages **23** for patients in a hospital ward or long-term care facility ward could be organized by room number in the order in which the drugs **21** are to be administered to the patient in each room.

As an alternative, the pouch packages **23** can be loaded with drugs **21** not associated with any prescription order. For example, the pouch packages **23** may be loaded serially with identical drugs **21** such as a commonly-provided pain medication.

Referring again to FIGS. **1-13**, exemplary automatic drug packaging machine **11** includes a housing **27** with top and bottom walls **29, 31**, left and right sidewalls **33, 35**, and front and rear walls **37, 39**. Automatic drug packaging machine **11** may be supported on a floor by legs **41**. A touch-screen video display (not shown) may be mounted to housing **27** and may include controls permitting a technician or pharmacist to control operation of the automatic drug packaging machine **11** and to receive information about the status of the drug fulfillment process.

Exemplary automatic drug packaging machine **11** includes twenty pull-out drawers. For convenience and brevity, reference number **43** is used for each drawer. In the example, the drawers **43** are organized into five rows of four drawers. As illustrated schematically in FIG. **6A**, each drawer **43** supports a plurality of cassettes which may be removable from the respective drawer **43**. The cassettes **45** are also referred to in industry as "canisters."

Each cassette **45** stores a quantity of loose, flowable drugs **21**. The drugs **21** are typically in a form referred to as a "tablet." The tablet-form drugs **21** may be in any shape including capsules, spheres, ovals, disks, multi-angles, squares, triangles, ellipses, and the like. The tablet-form drugs **21** could be provided as single-dose tablets or as partial dose tablets. For example, tablets could be cut in half to provide a half-strength dose of the drug **21**. While not illustrated, an automatic drug packaging machine **11** embodiment could also be configured to dispense drugs in forms other than tablets, such as granular or powdered form. The cassettes **45** can be replenished as drugs **21** stored therein are depleted.

As illustrated schematically in FIG. **6A**, each cassette **45** may be associated with a motorized base **47**. Each base **47** may be supported on one of the pull-out drawers **43**. This arrangement permits a technician to easily pull out a drawer **43** to service any base **47** and to remove any cassette **45** for drug **21** replenishment.

Each motor base **47** may be activated to dispense the needed drug quantity for each pouch package **23**. The motor base **47** may include a rotatable platen (not shown) or rotatable comb (not shown) which meters (i.e., singulates) drugs **21** from a cassette **45** one-after-the-other. The motor base **47** includes a counter **49**, which may be an infra-red emitter and detector pair, which registers a count each time a drug **21** passes the counter **49**. The count is used to control operation of the motor base **47** (i.e., turn the motor base **47** "off") so that the correct quantity of drugs **21** is dispensed from cassette **45** for each pouch package **23**.

Automatic drug packaging machine **11** may include apparatus other than plural cassettes **45** for storing and dispensing drugs **21**. For example the automatic drug packaging machine **11** could store and dispense drugs **21** from an exception

storage apparatus (not shown), also referred to as a universal tray. An exception storage apparatus may be a pull-out device with drugs 21 stored in separate apparatus compartments. The exception storage apparatus dispenses the stored drugs 21 one-after-the-other under control of the automatic drug packaging machine 11. The exception storage apparatus may be particularly effective in dispensing partial dose tablets, such as the previously-described tablets which have been cut in half to provide a half-strength dose of the drug 21.

FIG. 6 schematically illustrates a packaging apparatus 51 located within automatic drug packaging machine housing 27. Packaging apparatus 51 packages drugs 21 dispensed from cassettes 45 into separate packages 23 to generate the pouch package web 25. In the example, packaging apparatus 51 includes a roll (not shown) of the material used to generate the pouch package web 25. The material used for web 25 may be a lightweight low density polyethylene ("LDPE") film. The exemplary packaging apparatus 51 further comprises a hopper-like guide 53, a printer 55, and a sealer and perforation device 57. The operation of packaging apparatus 51 is carefully synchronized with operation of the cassette motor bases 47 to dispense and package drugs 21 in accordance with batch file information as described below so that the automatic drug packaging machine 11 can preferably produce any desired arrangement of pouch packages 23.

Referring to FIGS. 6 and 6A, drugs 21 dispensed in a singulated manner from the cassette 45 or other storage and dispensing apparatus may fall by means of gravity in the direction of the arrow through chutes (not shown) toward guide 53 of packaging apparatus 51. Guide 53 directs each drug 21 into the pouch package web 25. Guide 53 may include a counter 59 positioned in a path of drug 21 movement toward the pouch package web 25. Counter 59 may be a infra-red emitter and detector pair such as counter 49 provided on cassette base 47. Counter 59 registers a count each time a drug 21 passes counter 59 as the drug moves through guide 53.

The count generated by guide 53 counter 59 and the count from cassette base 47 counter 49 may be compared to the count required for the pouch package 23 to confirm that an identical quantity of each drug 21 dispensed from the cassette 45 has been loaded into the pouch package web 25 and that the counts from counters 49, 59 match the count required by the prescription order. This comparison of counts from counters 49, 59 is useful because drugs 21 can sometimes become lodged in the automatic drug packaging machine 11 and may not enter the pouch package web 25. A record of the counts from counters 49, 59 may be stored in a batch file associated with each pouch package 23. The batch file, including a subfile for each pouch package, may reside in a database in non-volatile memory 17 of computer 15. Each subfile may contain other information for the corresponding pouch package 23, examples of such information being described herein.

Referring further to FIG. 6, packaging apparatus 51 forms by folding a pocket 61 in pouch package web 25 as the web 25 is unwound from the supply roll (not shown). The pouch package web 25 is folded in half to form the pocket 61.

As illustrated in the example of FIG. 6, the web 25 may include a portion 63 which receives printed information thereon and a transparent portion 65. Once the pouch package 23 is formed in pouch package web 25, portion 63 becomes a first side 67 of pouch package 23 and the transparent portion 65 becomes a second side 69 of pouch package 23. Portion 63 preferably contrasts with printed information applied thereto and facilitates reading or machine detection (e.g., barcode recognition or optical character recognition) of the printed

information. The transparent portion 65 permits each drug 21 to be easily viewed and imaged within each pouch package 23 for the purpose of creating an image record of the contents of each pouch package 23 as described herein.

In the example, the printer 55 shown schematically in FIG. 6, prints information on the folded web 25 portion 63 adjacent the location where each pouch package 23 will be formed before each drug 21 for a pouch package 23 is loaded into pocket 61 from guide 53. Another type of information-application device could be used in place of a printer 55. Advancement of the web 25 is stopped momentarily so that printer 55 may apply printed information 70 to the web 25 adjacent where each pouch package 23 will be formed in web 25.

As illustrated in FIGS. 16A, 16B, and 16E, printer 55, in synchronized operation with automatic drug packaging machine 11, may also print information 70 to provide an empty header package 72 (72a in FIG. 16E) indicative of the commencement of one or more pouch packages for a patient and information 70 to provide an empty trailing package 74 indicative of the end of the pouch package 23 for a patient. The header and trailing packages 72, 74 are useful to assist personnel in distinguishing the pouch packages 23 of one patient from the pouch packages 23 of another patient.

As illustrated in the example of FIGS. 15A, 16A, 16B, and 16E the information 70 applied to pouch package web 25 portion 63 may include any information deemed appropriate. The information 70 may include: the patient name 71, instructions for taking the drug 73 (e.g., date and time of day), drug information 75 (e.g., drug name, drug strength, drug appearance information, drug quantity, lot number, and expiration date), and a machine-readable code 77. Any combination of this information 70 or other information may be implemented by the pharmacy. The machine-readable code 77 may uniquely identify each pouch package 23. In the example, machine-readable code 77 is compared for a match with an expected code in a batch file subfile for the pouch package 23 for purposes of pouch package 23 verification as described below.

The machine-readable code 77 may be any suitable form of code. Each machine-readable code 77 illustrated in FIGS. 15A and 16B-16C is a barcode. If a barcode is selected as machine-readable code 77, the barcode may be of any format including, without limitation, Universal Product Code ("UPC"), Code 39, and PDF417. Other types of machine-readable code 77 may be utilized. For example, a radio frequency identification ("RFID") tag could be placed on or in each pouch package 23 to uniquely identify the pouch package 23. By way of further example, optical character recognition ("OCR") could be used in place of, or in addition to, a barcode or another form of machine-readable code 77.

In another embodiment illustrated in FIG. 16E, some or all of the information 70 may be on the transparent pouch package 23a second side. In this embodiment, printer 55 may apply some or all of the information 70 to the transparent portion 65 of pouch package web 25 during pouch package 23a generation. In such embodiments, the side 67 of pouch package web 25 preferably provides a background which clearly contrasts with the information 70 on pouch package 23a side 69 so that such information 70 can be easily read by a human or be capable of detection by a code reader or other device. By providing information 70 on the pouch package 23a transparent side 69, it would be possible to simultaneously view, or capture an image of, both the information 70 and appearance of each drug 21 on the same side of the pouch package 23a.

Referring again to FIG. 6, the packaging apparatus 51 fills, or loads, the drugs 21 into the pocket 61 formed in web 25

adjacent the corresponding printed information **70** (e.g., patient name **71**, instructions **73**, drug information **75**, machine-readable code **77**, etc.) on web **25**. Guide **53** guides each drug **21** into pocket **61**. Dispensing of each drug **21** from a cassette **45** (or other storage and dispensing apparatus) for each pouch package **23** and loading of each drug **21** into the pocket **61** is synchronized with printing by printer **55**. At the same time that web **25** is momentarily stopped for printing, drugs **21** are loaded into pocket **61** downstream from printer **55** adjacent the corresponding printed information **70** (e.g., patient name **71**, instructions **73**, drug information **75**, machine-readable code **77**, etc.) for the pouch package **23** into which each drug **21** is loaded.

A sealer and perforator unit **57** shown schematically in FIG. **6**, is used to seal each drug **21** into a discrete, separate pouch package **23** formed in the pouch package web **25**. Sealer and perforator unit **57** may seal web **25** into separate pouch packages **23** by advancing web **25** between heated sealing rollers (not shown) or by other means, such as sonic welding. The sealer and perforator unit **57** may also perforate web **25** making a perforation line **79** between each adjacent pouch package **23** to permit each pouch package **23** to be easily separated from the pouch package web **25** by tearing. In embodiments, the automatic drug packaging machine **11** may be capable of generating a separate pouch package **23** approximately every one second.

In addition to formation of pouch packages **23** and header and trailing packages **72**, **74**, automatic drug packaging machine **11** and packaging apparatus **51** may process web **25** in other manners. For example, and as shown in FIG. **16F**, automatic packaging machine **11** and packaging apparatus **51** could provide a "message package" **76** in the pouch package web **25** for a series of pouch packages **23** for a patient. A message package **76** may comprise an empty package **76** between pouch packages **23**. Information **70** useful to the patient or care giver may be provided on the message package **76**.

Any information **70** useful to the patient or care giver may be provided on the message package **76**. Information **70** may be provided from the patient's prescription order or any other source. As illustrated in the example of FIG. **16F**, the information **70** provided on exemplary message package **76** advises the care giver to take the patient's vital signs before administering drugs **21** supplied in pouch package **23**. By way of further example, the message package **76** may provide instructions to the patient for taking the drug **21** in the pouch package **23** adjacent to the message package **76**.

Any number of message packages **76** may be provided. Preferably, the message packages **76** and information **70** thereon are created as part of the batch file containing the instructions used to operate automatic drug packaging machine **11** to package drugs **21** in the pouch packages **23**.

After pouch package **23** formation and packaging, the pouch package web **25** is output through port **81** in automatic drug packaging machine **11** front wall **37**. The port **81** is in communication with the package-less verification system **13** module **19**. In the example, the package-less verification system **13** receives each pouch package **23** and performs the package-less verification as described below.

In summary, the exemplary product of the automatic drug packaging machine **11** comprises a pouch package web **25**, or vine, of serially packaged pouch packages **23**. Header, trailing and instruction packages **72**, **74**, **76** may be included. Each pouch package **23** contains at least one dose of a drug or drugs **21**. Information **70** preferably provided by printer **55** may be on pouch package **23** first side **67** and each drug **21** in each pouch package **23** is easily viewable through the pouch

package **23** second side **69**. Alternatively, information **70** may be on second side **69** so that the information **70** and each drug **21** can be viewed simultaneously on the same pouch package **23**. Each pouch package **23** of web **25** can be ordered in any appropriate manner and can be arranged serially by patient, or in the order in which the drug **21** doses are to be administered.

Verification System

Verification system **13** will now be described in connection with FIGS. **1-5** and **7-13A**. The exemplary verification system **13** automatically provides verification that each drug **21** in each pouch package **23** is correct in accordance with a patient prescription order, or as otherwise required by the pharmacy. In the example, the verification system **13** implements a first package-less verification by means of code comparison and a second package-less verification by means of image comparison. The image comparison can be performed in real time as pouch packages **23** are packaged, or at a time subsequent to packaging of the pouch packages **23** utilizing stored image and other data for each pouch package **23**. The verification processes provide for more complete assurance that the correct drug **21** has been provided to the patient in accordance with the patient's prescription order, thereby improving patient care. Further, the stored image and other data provide a record of proper packaging of each pouch package **23**.

In the example, verification system **13** module **19** includes a housing **83** with top and bottom walls **85**, **87** left and right sidewalls **89**, **91**, and a front **93** wall. Front wall **93** includes a port **123** through which pouch packaging material web **25** including pouch packages **23** is output from the automatic drug packaging and package-less verification system **10**.

Module **19** may be attached to automatic drug packaging machine housing **27** by a piano hinge **94**. Hinge **94** permits module **19** to swing to an open position shown in FIG. **5** for maintenance or cleaning. Module **19** is a particularly convenient way to retrofit an automatic drug packaging machine **11** with a package-less verification system **13**. It is expressly contemplated that the invention may be embodied solely as a package-less verification system **13** and methods of use of same.

An electronic door interlock (not shown) may optionally be provided to ensure that the module **19** housing **83** remains in the closed position shown in FIGS. **1-4** against automatic drug packaging machine front wall **37** during operation of the system **10**. This avoids tearing or breaking of the web **25** of pouch packages **23** during operation.

Housing **83** of module **19** may be provided to enclose components of the verification system **13**. In the example, components within housing include an imager **95** consisting of first and second imaging devices **97**, **99**, a code reader **101**, lamps **103**, **105**, shroud **107**, a web drive system **109**, a servo motor controller **111** for control of web drive system **109** servo motors **120**, **122**, a power supply **112**, a communications hub **114**, and a terminal block **116**. Power supply **112** provides electrical power to the imaging devices **97**, **99** of imager **95**, code reader **101**, lamps **103**, **105**, servo motor controller **111**, servo motors **122**, **124**, marking device **141** (or **141a**) and any other electrical components. Communications hub **114** provides an interface by which imaging devices **97**, **99** of imager **95**, code reader **101**, servo motor controller **111**, and marking device **141** or **141a** are in data-transmission relationship with computer **15**. The program of instructions executed by computer **15** controls operation of these components. The data-transmission relationship between computer **15** and components **95**, **97**, **99**, **101** and **111**, **141**, **141a** may be

provided in any suitable manner. A terminal block **116** may be provided in module **19** for purposes of making electrical connections among the aforementioned verification system **13** components.

Referring to FIGS. **7-13A**, imager **95** may be provided adjacent web path **110** to capture an image of each pouch package side **67, 69** to thereby create an image record of the pouch package **23** at the point of packaging by automatic drug packaging machine **11**. While imager **95** is illustrated with two imaging devices **97, 99**, it should be understood that any suitable type or number of devices may be provided to create the image record of the pouch package **23** at the point of packaging. In the example, imaging device **97** may be provided to capture an image **169** of the pouch package first side **67** and any information **70** thereon (e.g., patient name **71**, instructions **73**, drug information **75**, machine-readable code **77**, etc.) and imaging device **99** may be provided to capture an image **171** of the pouch package **23** transparent second side **69** so as to create a record of each drug in the pouch package **23**. The image data corresponding to each image are transmitted to computer **15** via communications hub **114** for storage in the batch file subfile corresponding to the pouch package **23**.

In a further embodiment, imager **95** may include one operating imaging device **99**. Such an arrangement could be utilized with a pouch package **23a** of the type previously described in connection with FIG. **16E** wherein the information **70** and drugs **21** can be simultaneously viewed through one side **69** of the pouch package **23a**. In such an arrangement, a single imaging device would capture the image **171**. Imaging device **97** would not be necessary in this example. Imaging device **97** may be provided in such an embodiment, but may be disabled for use of verification system **13** with the type of pouch package **23a** illustrated in FIG. **16E**.

Imaging devices **97, 99** may each be a charged coupled device ("CCD"). The preferred CCD captures light and converts it to digital data that is stored through processing in each subfile for each pouch package **23** by computer **15**. It is preferred that each imaging device **97, 99** has a resolution of about 4 to 8 Megapixels. Each imaging device **97, 99** is preferably cycled at a rate sufficient to gather the necessary image data **169, 171** (e.g., approximately 250 cycles/second).

Lamps **103, 105** may be any light source adequate for imaging of pouch packages **23** by imaging devices **97, 99**. Lamps **103, 105** are supported by support structure **113** within module **19**.

Code reader **101** is provided to read machine-readable code **77** on pouch package **23**. In an embodiment, code reader **101** may be a barcode reader capable of automatically reading the barcode-type machine readable code **77**. A barcode scanner or barcode reader is an apparatus which applies light such as a laser beam emitted from a light source toward a barcode portion and reads the barcode from an electronic signal obtained by receiving its reflected light. Barcode readers typically employ decoding circuitry to interpret the signals produced by a photodetector receiving the reflected light from the barcode symbol. Various types of bar code scanners are available including omni-directional scanners which use a series of straight or curved scanning lines of varying directions in the form of a starburst, a lissajous pattern, or other multi-angle arrangements which are projected at the barcode symbol assuring that the barcode is read at various orientations.

In another embodiment, code reader **101** may be a component integrated with imager **95** imaging device **97** or **99** capable of automatically reading the barcode-type machine readable code **77**. As is known, camera-based barcode readers

exist which utilize the camera to capture an image of a bar code. The barcode reader then uses sophisticated digital image processing techniques to decode the bar code. Camera systems incorporate robust decode software that reads 2D and linear bar codes on objects that are stationary or in motion. Decode software ensures the camera delivers the best possible read rates even on poor contrast bar codes. Interface targeting systems enable camera adjustments to accommodate changing production runs. The decoder can differentiate between codes in the camera's field of view or decode multiple codes simultaneously.

A support structure **113** within module **19** is provided to support imager **95** imaging devices **97, 99**, code reader **101**, and lamps **103, 105** with respect to the system **10**. The exemplary support structure **113** may include mounts **117, 119, 121** secured directly or indirectly to support structure **113**. Mounts **117, 119, 121** respectively support imaging devices **97, 99** and code reader **101** without any need for a human to hold a hand-held imaging device or code reader to perform the package-less verification. Referring to FIGS. **1-5** and **6-13**, the support structure **113** supports imaging devices **97, 99** comprising imager **95** with their lenses and sensors facing one another. In the embodiment, imaging devices are positioned to image the pouch package first and second sides **67, 69** as web **25** is advanced between imaging devices **97, 99** during verification.

Web drive system **109** may optionally be provided to advance web **25** along a web guide **110** in synchronization with web **25** output from automatic drug packaging machine **11**. Web drive system **109** advances web **25** between imaging devices **97, 99** from output of the web **25** through port **81** in front wall **37** of automatic drug packaging machine **11**, through module **19** along guide **110** and out module port **123**. Guide **110** may comprise an extrusion which partially supports web **25** for sliding across guide **110** as web **25** is advanced through module **19** by web drive system **109**. In the example, guide **110** permits unobstructed imaging of pouch package **23** first and second sides **67, 69** by imaging devices **97, 99**.

Drive system **109** includes a belt drive system with a first continuous belt **125** on idler rollers **127, 129** and a second continuous belt **131** on rollers, **133, 135** and a drive roller which is hidden in FIG. **12**. The drive roller drives belt **131** and is driven by servo motor **122**. A first servo motor **120** controlled by servo motor controller **111** powers one or both of rollers **133, 135** to synchronize advancement of web **25** with the packaging apparatus **51**. Belts **125, 131** may form a nip which grips an edge portion of web **25**. (FIGS. **7-13A** show belts **125, 131** spaced apart for loading of web **25** on web guide **110**.) Movement of powered belt **131** advances web **25** through module **19** along web guide **110**.

Belt **125** may be moved toward and away from belt **131** to permit web **25** to be led between the belts **125, 131** on guide **110** when loading the web **25** into module **19** to begin verification of a batch of pouch packages **23**. And, separation of the belts **125, 131** releases the clamping force applied by the belts **125, 131**, permitting module **19** to swing to the open position illustrated in FIG. **5** without tearing web **25**. The foregoing belt separation may be accomplished by mounting belt **125** rollers **127, 129** on a mount **137** which is capable of movement toward and, alternatively, away from web **25** and belt **131** in the directions of dual headed arrow **139**. Servo motor controller **111** controls a second servo motor **122** to move mount **137** alternatively in the directions of arrow **139**. Controller **111** can automatically move mount **137** away from belt **131** to release the force applied to web **25** to prevent

tearing of the web 25 when housing 83 is opened and swung away from front wall 37 as illustrated in FIG. 5.

Shroud 107 may be supported by support structure 113 within module 19 adjacent lamps 103, 105 to at least partially block and reflect light from lamps 103, 105 to prevent unwanted light migration from module 19 and to better illuminate pouch package 23 first and second sides 67, 69 for image capture by imaging devices 97, 99.

As illustrated in FIGS. 13 and 13A, a marking device 141 may be provided to place a mark (not shown) on each pouch package 23 determined to be potentially non-compliant at the time that the pouch package 23 is formed. The marking device 141 may include a marking tip 143 which extends to place the mark on the pouch package second side 69. The mark provided by the marking device 141 facilitates identification of the non-compliant pouch package 23 if it is necessary to retrieve the pouch package 23 from a group of look-alike pouch packages 23 in a pouch package web 25.

In an embodiment illustrated in FIG. 13A, a marking device 141a could be used in place of marking device 141. In the example, marking device 141a may apply more than one type of marking to a given pouch package 23. Marking device 141a is otherwise identical to marking device 141. Marking devices 141, 141a are preferably controlled by computer 15.

Marking device 141 or 141a could be utilized for purposes other than providing a marking indicating a non-compliant pouch package 23. For example, marking device 141a could be utilized to provide a classification code on the pouch package 23. A classification code may comprise a marking which provides some information or classification associated with the pouch package 23. For example, marking device 141a may be capable of applying more than one color to a pouch package 23 to color code the package 23. Marking device 141a could include any number of marking tips 143a, 143b, 143c with each tip capable of extension to apply a different color marking to a pouch package 23 under control of instructions executed by computer 15. The color coding may be set in the instructions for the pouch package 23 at the time of batch file generation. In the example, the classification code would be applied to the pouch package 23 as the pouch package web 25 is indexed along web guide 110 in contact with a marking tip or tips 143a, 143b, 143c.

By way of example, marking device 141a could be used to apply one color-type classification code (e.g., a green stripe) to a pouch package 23 intended to be administered at breakfast, another color-type classification code (e.g., a yellow stripe) to a pouch package 23 intended to be administered at lunch, and a further color-type classification code (e.g., a blue stripe) to a pouch package 23 intended to be administered at dinner. Application of a classification code to the pouch package 23 provides a further opportunity to improve the quality of patient care by assisting the patient to comply with a prescription order or other instructions.

Upon exiting module 19 port 123, the pouch package web 25 may be taken up by a spooler 145 as illustrated in FIG. 2. Spooler 145 takes up the pouch package web 25 from automatic drug packaging machine 11 by winding the pouch package web 25 onto spool 147 in the direction of arrow 148. The spooler 145 provides a convenient alternative to allowing the pouch package web 25 to simply fall onto the floor or into a tote. Each spool 147 may be detached from spooler 145. As illustrated in FIG. 14, each loaded spool 147, including a length of pouch package web 25 wound thereon, may be placed on a rack 149. Rack 149 may be wheeled to an appropriate location for administration of the drugs 21 to each patient. Spoolers 145 are described in commonly-owned U.S.

patent application Ser. No. 12/139,236, the contents of which are incorporated herein by reference.

If sold as a separate component, the package-less verification system 13 module 19 may be retrofit on a model ATP 128, 192, 256, 320, or 384 automated tablet packaging machine available from Chudy Group, LLC of Powers Lake, Wis.

Referring now to FIGS. 15A, 16A-16B and 16E-16F, a registration mark 150 may be provided to initiate image capture and reading of machine-readable code 77. Registration mark 150 may also facilitate complete image capture of the pouch package 23 and each drug 21 packaged in the pouch package 23, including for pouch packages 23 provided in different sizes.

The pouch packages 23 packaged by automatic drug packaging machine 11 and verified by verification system 13 may be provided in the pouch package web 25 in a single size or in different sizes. Different pouch package 23 sizes may be selected based on the quantity of drugs 21 to be packaged in each pouch package 23. The size of each pouch package 23 may be selected from a plurality of package sizes based on a setting in each subfile for each pouch package 23 upon creation of the batch file with instructions for loading each pouch package 23. By way of example, the pouch package 23 sizes may be small, medium, or large. Automatic drug packaging machine 11 controls printer 55 (or other information-application device) and movement of web 25 so that the printed or otherwise applied information 70 (e.g., patient name 71, instructions for taking the drug 73, drug information 75, and machine-readable code 77) is located approximately at the middle of the pouch package 23 for each of the small, or medium, or large package sizes.

As previously described, imager 95 imaging devices 97, 99 strobe continuously. Each strobe cycle represents a separate image. System 10 may be configured so that the only images of pouch package 23 first and second sides 67, 69 saved in each pouch package 23 subfile are the images 169, 171 in which the printed information on the first side 67 and second side 69 are properly centered for imaging devices 97, 99. Centering provides the opportunity to capture a complete image of the information on the first side 67 and drugs 21 viewable through the second side 69.

In order to identify to computer 15 which image to store in each subfile, a registration mark 150 may be provided as part of the printed information. The registration mark 150 is detectable by the first imaging device 97. The registration mark 150 is a marking or symbol which is recognized by the instructions residing in memory 17 of computer 15 for purpose of capturing the images with imaging devices 97, 99 when the information on pouch package 23 is properly centered in front of the first imaging device 97. Since second imaging device 99 faces first imaging device 97 and web 25, centering of first imaging device 97 on the printed information also centers the second imaging device 99 on the pouch package 23. The instructions executed by computer 15 capture the image of the pouch package first side 67 and, preferably, the image of the pouch package second side 69 responsive to detection of the registration mark 150. The instructions executed by computer 15 may further read the pouch package machine-readable code 77 with code reader 101 responsive to detection of the registration mark 150.

As illustrated in FIGS. 15A, 16A, 16B, 16E, 16F, and 17, the registration mark 150 may be a darkened rectangle located adjacent the printed information 70 including: patient name 71, instructions 73, drug type 75, and machine-readable code 77. As is apparent from FIGS. 15A, 16A, 16B, 16E, 16F, and 17, such information is generally centered on the first side 67 of each pouch package 23. The registration mark 150 appears

17
18

in the same proximity to such printed information for each of the small, medium, or large size pouch packages **23**.

In an embodiment, the instructions executed by computer **15** may be configured to save the images of the pouch package first and second sides **67**, **69** generated at a preset time, or number of strobe cycles, responsive to detection of the registration mark **150** by imaging device **97**. Each saved image **169**, **171** of the pouch package first and second side **67**, **69** is stored in the subfile for the pouch package **23**. Consequently, the captured images of the pouch package first and second sides **67**, **69** may always be generally centered on the pouch package **23** and a complete image record created and saved of such first and second sides **67**, **69** for each of the different pouch package sizes (e.g., small, medium, or large pouch package sizes). The registration mark **150** can also be used in pouch package **23**a embodiments such as shown in FIG. **16**E in which the information **70** is on the transparent second side **69**.

Exemplary Systems

Referring now to FIGS. **17**, **18**A and **18**B, those figures schematically illustrate that exemplary automatic drug packaging machine and package-less verification system **10** may interface with various workstations **151**, **153** and components, such as video displays **152**, **157** and input devices **155**, **159**. For example, a data entry workstation **151** and a verification workstation **153** may be provided. Data entry workstation **151** may include a video display **152** and one or more input device **155** for inputting information to a computer **156**. Input device **155** may be one or more of a keyboard, a mouse, a touch screen video display, a code reader, or any other suitable device. Data entry workstation **151** may be provided for creation of batch files. Each batch file includes all instructions necessary to control operation of system **10** to package one or more pouch package **23**, including any related packaging such as header or trailing packages **72**, **74**, message packages **76** and information **70** applied to such packages **23**, **72**, **74**, **76**. Preferably, each batch file has related subfiles that each include data relating to one pouch package **23**, or header or trailing package **72**, **74**, or message package **76**.

It will be understood that a file, batch file, or subfile are intended to be broad terms which mean or refer to one or more elements of data stored in memory which may be recalled by the system **10**. It will be further understood that multiple memory locations may be utilized for storing the data elements relating to each file, batch file, or subfile. Therefore, the terms file, batch file, or subfile as used herein refer to the data elements for any given pouch package.

Verification workstation **153** may include a split screen touchscreen video display **157** (FIG. **17**) and one or more input device **159** for inputting information to a computer **161** and to computer **15**. Input device **159** may be one or more of a keyboard, a mouse, a touch screen video display, a code reader, or any other suitable device. Video display **157** displays generated data for a pouch package **23** to a user at workstation **153**.

Data entry workstation **151** and verification workstation **153** may be connected to computer **15** for data transmission in any suitable manner such as by local area network ("LAN"), wide area network ("WAN"), by a pharmacy information system **162** used to control operation of the overall pharmacy, and by the Internet **163**.

Verification workstation **153** may be co-located with system **10** or may be located at a location remote from (i.e., spaced from) system **10**. And, verification workstation **153** could be both co-located with system **10** and located at a location remote from system **10**. This arrangement permits pharmacist prescription order verification at virtually any location, including a location in a city or state far from the location at which system **10** packages the pouch packages **23**. Further, this arrangement permits pharmacist prescription verification without the presence of the pouch package **23** at the first or second location and without the necessity that the pharmacist physically handle the pouch package **23**.

Exemplary Operation

Operation of the exemplary automatic drug packaging machine and package-less verification system **10** will now be described in connection with the exemplary flow diagrams of FIGS. **19**A and **19**B. The exemplary process may include a first verification process and a second verification process. The first verification process preferably comprises an automatic code comparison at the point of packaging involving comparison of a code associated with a pouch package **23** and an expected code for the pouch package **23**. The second verification process is preferably based on an image comparison of the pouch package **23** and its drug **21** contents against a reference image and other stored information for the pouch package **23**.

The first and second verification process may occur in what is referred to herein as a "real time" verification mode in which both the first and second verification process occur at or shortly after each pouch package **23** is packaged by system **10**. The second verification process may also occur in what is referred to herein as a "delayed time" verification mode in which the second verification process occurs at a point in time subsequent to the time that the pouch packages **23** are packaged by system **10**. In the delayed time verification mode, the pouch packages **23** are packaged and the user relies on the information in each file for the pouch package **23** to perform the verification. Use of the terms real time and delayed time for the verification is done for convenience and is not intended to impose any particular limitations.

Both the first and second verification process may be considered "package-less" because the verification occurs without the necessity to physically handle or touch the drug **21** or pouch package **23** during the verification process.

In the example, the process is controlled by a program of instructions residing in computer **15** non-volatile memory **17**. The process may be carried out by a computer program product, comprising a computer usable medium having a computer readable program code embodied therein. Execution of the computer readable program code would implement the process.

The process may be entered at Start **301** and includes a user login for continuing a data entry process. At block **303**, a user creates a batch file at a data-entry workstation **151**. The data entry workstation **151** may be directly or indirectly connected for data transmission to computer **15**. A "user" of workstation **151** may be any of the pharmacy personnel authorized to enter data used to create the batch files. The batch files may be created from one or more prescription orders. The user at workstation **151** uses input device **155** for data entry of the batch files into a database. In this example, the database may reside in non-volatile memory **17** of computer **15**. Persons of skill in the art will appreciate that the database of batch files may reside at any location on the network to which the system **10** may be connected for data transmission.

A batch file created in block **303** comprises a group of data elements that relate to a specific group of pouch packages **23**. The batch file may further comprise a separate file containing a group of data elements that relate to each specific pouch

package 23. The batch file may include any number of these separate files. For convenience, each separate file or data element relating to a specific pouch package 23 is referred to herein as a subfile. The batch file or subfiles may be supplemented with the data generated by the verification processes described herein to create a complete record of the packaging of each pouch package 23 and the status of the pouch package 23 as verified or non-verified. Data elements for each pouch package may be recalled from the batch file or subfiles for subsequent review and action as appropriate.

The data elements in each subfile include all information necessary to fully process each pouch package 23. These data elements may include the drug 21 to be packaged in the pouch package 23 and a unique code identifying the pouch package 23 and which matches fully or in part to the machine-readable code 77 which, in the example, is to be printed on the pouch package 23 first side. The data elements may further include the patient name, instructions for taking the drug (e.g., date and time of day), and drug information (e.g., drug name, drug strength, drug appearance information, drug quantity, lot number, and expiration date), as well as any other relevant information. The data elements may include other information needed including information for generation of the header, trailing, and message packages 72, 74, 76 and all information and instructions thereon. The data elements may include whether to place a color code on a pouch package 23 by means of marking device 141a. The data elements may also include package 23 size, for example, small, medium, or large size packages.

The subfiles within the batch file may be arranged in any manner. The subfiles may be organized to facilitate patient compliance with the physician's instructions as set forth in a prescription. To this end, the subfiles may be organized and arranged so that each pouch package 23 and the drug 21 in each pouch package 23 are in the order in which each drug 21 is to be taken. By way of further example, the subfiles may be organized in the order in which each drug 21 is to be administered to the patients within rooms of a hospital ward or long-term care facility ward. As yet a further example, the subfiles could be organized to serially load an identical drug 21 into a series of pouch packages 23.

At block 305, a user releases a batch file for processing by the automatic drug packaging machine 11 of system 10. (In FIG. 19A, automatic drug packaging machine 11 is referred to as "ATP") The computer 15 transmits the batch information to the automatic drug packaging machine 11. System 10 may be set in a real time verification mode or a delayed time verification mode.

At block 307, the automatic drug packaging machine 11 dispenses and packages each drug 21 required by a subfile. Printer 55 of the automatic drug packaging machine 11 prints any suitable information 70 on the pouch package web 25 preferably centered adjacent where the pouch package 23 will be formed. The information may include: the patient name 71, instructions for taking the drug 73 (e.g., date and time of day), drug information 75 (e.g., drug name, drug strength, drug appearance information, drug quantity, lot number, and expiration date), and machine-readable code 77. This information will preferably appear on the pouch package 23 first side 67, or second side 69, as previously described. Any classification code, such as color coding or other marking, may be applied by marking device 141a to the pouch package 23 at block 307.

As previously described, one or more drug 21 required by the subfile is dispensed from a cassette 45. Packaging apparatus 51 fills the pouch package web 25 with each drug 21. Sealer and perforator unit 57 seals the web 25 to form each discrete pouch package 23 and provides perforation line 79 in

web 25 adjacent the pouch package 23. As appropriately sequenced by the batch file information relative to the pouch package 23, block 307 also results in sequenced generation of an empty header, trailing or message package 72, 74, 76 as previously described. Such packages 72, 74, 76 respectively indicate the beginning and end of a group of pouch packages 23 for a patient, and instructions or other useful information relating to the prescription order.

At block 309, the automatic drug packaging machine 11 packaging apparatus 51 indexes the pouch package web 25, to permit loading of the next pouch package, thereby elongating the pouch package web 25.

At decision point 311, the instructions executed by computer 15 determine whether a registration mark 150 indicative of a pouch package 23 has been detected by first imaging device 97 of imager 95. Imaging device 97 strobes at an appropriate rate to gather the necessary image data awaiting detection of the registration mark 150. Preferably, the registration mark 150 is positioned so that the pouch package 23 will be in proper position for complete first and second side 67, 69 imaging irrespective of the pouch package size (e.g., small, medium, large size) as previously described. The determination of registration mark 150 detection is made during each strobe cycle of imaging device 97 in the example. If no registration mark 150 is detected in a cycle, the process returns to block 307. The image captured in each cycle is not saved. If a registration mark 150 is detected in the cycle, the process advances to block 313. At block 313, the instructions executed by computer 15 in the example cause imager 95 first imaging device 97 adjacent the pouch package web 25 to capture an image of the information 70 on pouch package 23 first side (e.g., patient name 71, drug instructions 73, drug information 75, and machine-readable code 77) responsive to detection of the registration mark 150 at decision point 311. Detection of the registration mark 150 at decision point 311 also causes second imaging device 99 adjacent the pouch package web 25 to capture an image of each drug 21 within the pouch package 23 through the transparent pouch package second side 69. These two captured images are saved in the subfile for the pouch package 23 in the database which may reside in memory 17 of computer 15. If a pouch package 23a is used as in FIG. 16E and the information 70 and drug 21 are simultaneously viewed on a single package side 69, then only a single image 171 would be captured and stored in the pouch package subfile.

At block 315, the instructions executed by computer 15 cause code reader 101 to read, or capture, the machine-readable code 77 of the pouch package 23 responsive to detection of the registration mark 150 at decision point 311. Reading, or capturing, of the machine-readable code 77 preferably occurs simultaneously with image capture by imaging devices 97, 99. Therefore, if code reader 101 is a barcode reader and the machine readable code 77 is a barcode, the code reader 101 reads the barcode and the barcode is saved in the subfile for the pouch package 23 in the database which may reside in memory 17 of computer 15.

As a result of the exemplary actions at blocks 313 and 315, the images 169, 171 of the pouch package first and second sides 67, 69 and the code corresponding to the machine-readable code 77 are all associated with the subfile for the pouch package 23 in the database which may reside in memory 17 of computer 15. The subfile may be a part of the batch file including each other subfile. The subfile now includes data related to each drug 21 expected to be loaded into the pouch package 23, the code corresponding to the

machine-readable code **77** and an image **169**, **171** and machine-readable code **77** record of the pouch package **23** as output from the system **10**.

First Verification Process

At decision point **317**, the first pouch package **23** verification process is initiated. At decision point **317**, the instructions executed by the computer **15** compare the code information in the pouch package **23** subfile for a match. The codes compared are preferably the code entered into the subfile at the time of batch file creation and the machine-readable code **77** actually read by the code reader **101**. Data is generated responsive to whether the codes match. The data include at least a verification of the pouch package **23** if the codes match and, alternatively, a non-verification of the pouch package **23** if the codes do not match. The generated data may comprise a control signal which controls operation of system **10** responsive to whether the codes match. Because of the high degree of operational accuracy of automatic drug packaging machine **11**, it is correct to conclude that if the machine-readable code **77** is verified as correct, then the other information **70** (e.g., patient information **71**, drug instruction information **73**, and drug information **75**) on the pouch package **23** is correct and that each drug **21** in the pouch package **23** is also correct.

The comparing and data generation at decision point **317** may occur automatically after reading the pouch package machine-readable code at block **315**. Preferably, the comparing and data generation occurs before the pouch package **23** exits the exemplary module **19** of the verification system **13**.

Comparing and data generation as the pouch packages **23** are packaged, or shortly thereafter, provides immediate information to the pharmacy indicative of a potential error associated with the pouch package **23**. This information provides the pharmacy with the opportunity to correct the error before a large number of potentially incorrect pouch packages **23** are processed. For example, a code mismatch could indicate the pouch package **23** is out of sequence and contains an incorrect drug **21**. A code mismatch could also indicate a printer **55** malfunction, potentially rendering each pouch package **23** of the pouch package web **25**, or vine, unusable. The pharmacist or pharmacy personnel is empowered to take steps to correct these problems.

At decision point **317**, pouch packages **23** for which there is a code mismatch do not proceed to image verification. Pharmacy personnel are required to resolve the reason for the code mismatch in this example.

The instructions executed by computer **15** may create a record of the pouch package verification or non-verification based on the result of the code comparison at decision point **317**. The record of the pouch package verification or non-verification is most preferably created in the subfile for the pouch package **23**, thereby creating information in database residing in memory **17** that can later be recalled to confirm the contents of each pouch package **23**.

Block **319** is entered to create a record if the code comparison at decision point **317** indicates there is no match and the status of the pouch package **23** is non-verified. Block **319** starts a process for resolution of the problem indicated by the code mismatch. The process provides immediate error detection so that the user can immediately take corrective action, thereby avoiding generation of an incorrectly-packaged web **25**.

At block **319**, the subfile for the pouch package **23** is updated to create a record of the mismatch and the occurrence is logged in the subfile by setting a non-verified state for the pouch package.

Also at block **319**, information may be provided to the user to indicate the code mismatch at decision point **317**. For example, the instructions executed by the computer **15** may be set to generate an audible or visual alarm if the codes do not match. The alarm would alert a user in real time of the potential error and enable the user to resolve the potential error, if desired.

At decision point **320**, the instructions executed by computer **15** make a determination regarding whether the process is in the real time verification mode or the delayed time verification mode.

Decision point **321** is entered if the process is in the real time verification mode. At decision point **321**, a determination is made regarding whether to immediately resolve the potential error indicated by the code mismatch at decision point **317**.

Block **323** is entered if the result of decision point **321** is to immediately resolve the potential error. Resolution also involves providing a correct pouch package **23** for the prescription order if necessary so that the prescription order is correctly fulfilled. At block **323**, the instructions executed by the computer **15** may be set to stop further operation of the automatic drug packaging machine **11** if the codes do not match. Stopping of the automatic drug packaging machine **11** would permit pharmacy personnel to resolve the potential error before proceeding with further packaging.

At block **325**, actions are taken responsive to resolution of the code mismatch at block **323**. At block **325**, the subfile of the pouch package **23** is updated to create a record of the error and the occurrence is preferably logged in the subfile by indicating the nature of the potential error and resolution to create a record for the pouch package **23**. The process for the real time verification mode proceeds to decision point **326** as described below.

Returning to decision point **321**, if the process is in the real time mode (decision point **320**) and the result of decision point **321** is to not immediately resolve the potential error or to take a further action responsive to the potential error, then the process moves to block **327**. A "no" decision at decision point **321** represents a determination that the system **10** should continue to operate notwithstanding detection of the mismatch at decision point **317**. The pharmacy will resolve the mismatch at a future time.

At block **327**, actions may be taken to identify the non-verified pouch package for future corrective action. For example, the instructions executed by the computer **15** may be set to provide a modification of the pouch package **23** if the codes do not match. In an embodiment, the modification provided may be an identification mark made on the pouch package **23** by marking device **141**. The identification mark applied to the pouch package **23** by marking device **141** indicates that the pouch package **23** may be incorrect and requires subsequent retrieval and attention before the drug **21** content can be administered to the patient.

As an alternative to marking (or in combination with marking), the instructions executed by computer **15** may be set to take other actions responsive to a code mismatch at decision point **317**. For example, the instructions executed by the computer **15** may be set to modify the pouch package **23** in ways other than by marking. For example, the pouch package **23** could be modified in some physical and detectable manner by notching or cutting the pouch package **23** with a cutter or punch (not shown) for later identification and automated

retrieval. The process for the real time verification mode proceeds to decision point **326** as described below.

Returning to decision point **320**, if the instructions executed by the computer **15** determine that the process is in the delayed time verification mode (a "no" decision at decision point **320**), the process immediately enters block **327** and carries out the steps to mark or otherwise identify the pouch package as described above in connection with block **327**.

Decision point **326** is entered from block **325** for the real time verification mode and from block **327** for both the real time verification mode and delayed time verification mode in the example.

At decision point **326**, the instructions executed by the computer **15** determine whether the pouch package **23** is the last file in the batch and whether additional pouch packages require packaging. If additional pouch package **23** subfiles of the batch file remain to be packaged, the process loops to block **309** and packaging by the automatic drug packaging machine **11** continues. If the pouch package subfile is the final subfile of the batch file at decision point **326**, then the process proceeds to block **328**.

At block **328** save log occurs and all data for the entire batch file is updated as saved in memory **17**, including pouch packages which had a code match at decision point **317** and were subsequently verified as correct during image verification in the real time verification mode. A record is created of each pouch package **23** which is non-verified as a result of the code mismatch at decision point **317** together with the resolution of such mismatch.

At block **328**, all data for pouch packages set for delayed time verification may be accessed as described in connection with FIG. **19B**.

The process then ends at end point **330**.

Returning to decision point **317**, the result of decision point **317** if the code comparison is a match is that the subfile for the pouch package is verified as correct. The pouch package subfile may optionally be updated to create a record of the match and verification. Absence of a record of any mismatch is also indication in the subfile that the pouch package is verified as correct.

Second Verification Process

The second verification process may be entered at FIG. **19A** decision point **329** for real time verification. The second verification process may separately be entered at FIG. **19B** entry point **401** for the delayed time verification mode.

Referring then to decision point **329**, the instructions executed by computer **15** make a determination regarding whether the process is in the real time verification mode or the delayed time verification mode. The process enters decision point **332** if the process is in the delayed time verification mode.

At decision point **332**, if additional pouch package **23** subfiles of the batch file remain to be processed, the process loops to block **309** and packaging by the automatic drug packaging machine **11** continues. The process continues until all pouch packages of the batch have been packaged. If the pouch package subfile is the final subfile of the batch file at decision point **332**, then the process proceeds to block **334**.

At block **334** save log occurs and all data for the entire batch file is updated as saved in memory **17**. The result of block **334** is that a record is created of each pouch package **23** which is verified as a result of the first verification and code match at decision point **317**. All data for the batch file is now available for pharmacist image review and verification in the delayed time verification mode as described in connection with FIG. **19B**. The process ends at **336**.

"Real Time" Verification

Returning to FIG. **19A** decision point **329**, if the instructions executed by the computer **15** determine that the process is in the real time verification mode, the process enters block **331** for real time image verification. The real time verification occurs as the pouch packages **23** are packaged by system **10** immediately after decision points **317** and **319**. In embodiments, the second image-based verification process could be performed in real time as each pouch package **23** is packaged and output by automatic drug packaging machine **11** and again at a subsequent point in time, for example as described in connection with FIG. **19B**, if a further level of verification is desired.

Before commencement of the image verification process, the pharmacist must first login to computer **15** or a pharmacy information system **162** in data-transmission relationship with computer **15**. The user may login with biometrics or password login with access granted based on the user security level. For example, a registered pharmacist would have the highest security level permitting the pharmacist to verify a prescription order while a pharmacy technician would have a lower security level permitting the technician to review pouch packages, but not verify a prescription order.

The image verification process may be performed at verification workstation **153** as previously described. As described in connection with FIGS. **18A** and **18B**, the workstation **153** may be at any user-designated location with workstation **153** in data-transmission relationship with computer **15**, for example via an Internet **163** connection as represented in the example of FIG. **18B**.

At block **331** and decision point **333** the second pouch package **23** verification process is initiated. In the example, this second pouch package **23** verification process comprises an image verification that the contents of the pouch package **23** are correct and fully in accordance with the prescription order or other instructions. As previously described, the second pouch package **23** verification process is package-less in the sense that it is based on review of saved data which may be in each subfile for each pouch package **23**. The process frees the pharmacist or other user from the necessity to physically handle or touch the drug **21** or pouch package **23** during the verification process. This greatly improves verification accuracy and the rate of processing.

At block **331**, the instructions executed by the computer **15** access the pouch package subfile and present generated data to the user on split screen touchscreen video display **157** as each pouch package is processed by system **10**. FIG. **17** illustrates an exemplary screen display of display **157** during verification. The user may be simultaneously presented with generated data including: text information **167** from the pouch package subfile including the unique identification code for the pouch package, each drug **21** of the pouch package **23** and any prescription information for the pouch package **23**, separate images **169**, **171** of the pouch package first and second sides **67**, **69**, and a reference image **173** of each drug **21** which should have been loaded in the pouch package **23**. One image of the pouch package **23** could be displayed if the text information and drug are visible through a single side **69** or of the pouch package **23**.

The text information **167** may include data relating to the color, shape or marking on the drugs **21** expected to be in the pouch package **23**. Such data may be provided in the subfile for the pouch package **23**. The reference image **173** called for

by information in the subfile also represents data relating to the color, shape or marking on the drugs because the reference image includes a graphic image of the physical appearance of the drug **21**. The reference image **173** (three shown in FIG. **17**) may be accessed over the Internet (e.g., Internet **163**) or from a separate database. Commercial sources of reference image databases are First Databank of San Francisco, Calif. and Medispan of Indianapolis, Ind.

Information **175** may also be displayed on display **157** indicating whether the pouch package **23** is verified or non-verified based on the first verification process. Such verification or non-verification information **175** could be displayed on display **157** as, for example, text or as a green indicator for verification and a red indicator for non-verification. The user may then compare and verify all of the displayed information on video display **157** for the pouch package **23**.

At decision point **333**, the instructions executed by computer **15** provide for comparing of information generated at block **331** and a determination of whether the information matches. In the example, the instructions executed by computer **15** provide for comparing at least the image **171** of the drugs within the pouch package **23** and a reference image **173** of each drug **21** which should have been loaded in the pouch package **23**. A pharmacist may make the determination of whether the displayed information matches. The pharmacist may, for example, push the match button **181** to indicate the match or may push the mismatch **179** button to indicate the result of the comparing. It is further envisioned that a computer may recall and compare the aforementioned data elements to make the same determination of whether the displayed information matches. Such computer comparison could occur at workstation **153** or elsewhere. This affirmative action of pushing the match buttons or mismatch buttons **181**, **179** results in data generation for the pouch package **23** responsive to whether the comparison is a match or mismatch. The data generation includes a verification of the pouch package **23** based on the match and, alternatively, a non-verification of the pouch package if there is not a match.

The instructions executed by computer **15** may create a record of the pouch package verification or non-verification based on the result of the image comparison at decision point **333** (and the code comparison at decision point **317**). The record of the pouch package verification or non-verification is most preferably created in the subfile for the pouch package **23**, thereby creating information in a database residing in memory **17** that can later be recalled to confirm the contents of each pouch package **23**. Absence of a mismatch record may be used to indicate that there was a match.

The process enters decision point **335** if the information does not match at decision point **333**. At decision point **335**, the user determines whether to pause the review and verification process to confirm the mismatch. The pharmacist or other user may push pause button **177** on touchscreen display **157** or otherwise operate a control to stop the automatic drug packaging machine **11** and verification system **13**.

Decision point **337** is entered if the user elects to pause verification at decision point **335**. At decision point **337**, the instructions executed by computer **15** again provide for comparing of all or any portion of the aforementioned data and a determination of whether the displayed information matches. Like the comparing at decision point **333**, the user (or a computer) confirms whether there is a mismatch of data displayed on video display **157**. The pharmacist or other user may push the mismatch button **179** on touchscreen display **157** or otherwise operate a control to indicate the mismatch and non-verification. If there is a match, the user may push a match button **181** and the process continues to decision point

345. This affirmative action of pushing the mismatch or match buttons **179**, **181** results in data generation for the pouch package **23** responsive to whether the comparison is a match or mismatch. The data generation includes a verification of the pouch package **23** based on the match and, alternatively, a non-verification of the pouch package if there is not a match.

Block **339** is entered if the mismatch is confirmed at decision point **337**. At block **339**, the instructions executed by the computer **15** may be set to provide a modification of the pouch package **23** if the codes do not match. In an embodiment, the modification provided may be an identification mark made on the pouch package **23** by marking device **141** or a physical change of the pouch package **23** which is detectable as previously described in connection with block **327** to indicate that the pouch package is potentially non-compliant and non-verified.

The result of an image mismatch at decision points **333**, **335**, and **337** and action in block **339**, is to create an image-based record of the mismatch in the pouch package subfile for the pouch package **23** indicative that the pouch package is non-verified.

Block **341** is next entered for the real time verification process. In block **341** the instructions executed by the computer **15** may be set to stop further operation of the automatic drug packaging machine **11** so that the image mismatch may be resolved. Stopping of the automatic drug packaging machine **11** would permit pharmacy personnel to resolve the potential error before further pouch packages **23** are loaded, thereby avoiding creation of a pouch package web **25** with numerous incorrectly-packaged pouch packages **23**.

Various options may be provided for creating a record of a non-verified and non-compliant pouch package **23**. Upon identifying a non-compliant pouch package **23**, a user may have the ability to flag and isolate by machine-readable code **77** that pouch package **23** for further review or for reference when removing the pouch package **23** from the pouch package web **25**. The capability of flagging pouch packages **23** makes it possible to easily access all records for any pouch package **23** believed to be non-verified and non-compliant with the prescription order and to review all non-compliant pouch packages **23** at one time. Each subfile for each non-compliant pouch package may be updated to indicate the non-compliance.

Non-verified and non-compliant pouch packages **23** may optionally be put into a quality control review queue through, for example, a "Move to Q.C." button on display **157**. The user may also have an option to select a "reason code" for any pouch package **23** determined to be non-verified and non-compliant and placed in the quality control queue. The quality control queue for each pouch package **23** may be updated by the user to indicate, for example, whether the printed information **70** (e.g., patient information **71**, drug instruction information **73**, drug information **75**, machine-readable code **77**) is illegible or incorrect, whether the drug **21** is not visible, whether the drug **21** is incorrect, whether the pouch package **23** is empty, and whether there is an under count or an over count.

The user may have the option to print a report of each pouch package in the quality control review queue. The report for each pouch package **23** may include, or not include, images **169**, **171** of the pouch packages **23**. Each pouch package **23** in the quality control queue may have associated with it the package first and second side **67**, **69** images **169**, **171**, the reason code, a resolution code for the pouch package **23**, the machine readable code **77** for the pouch package **23**, the batch name, patient name, facility, and storage cabinet name.

"Resolution codes" may include: pouch verified, pouch modified, pouch destroyed or pouch destroyed and regenerated. There may be an option to sign off on all quality control resolved pouch package 23 by user name and by biometric user identification.

The data in the quality control review queue may be used to generate trending reports, exception reports and the like that can be used for diagnostic purposes, such as to identify excessive cassette 45 misfeeds involving over or under dispensing. The trending reports can be used to locate and replace potentially defective cassettes 45 or other components.

A record of flagged pouch packages 23 where a discrepancy was noticed can be used to re-generate replacement pouch packages 23 based on batch file information relating to the flagged pouch packages 23. This allows the flagged pouch packages to be removed from the spool 147 and replaced with replacement pouch packages while maintaining the correct total spool 147 count.

Block 325 is entered once the source of the potential error has been identified and resolved. At block 325, the subfile of the pouch package is logged and updated with the data saved in computer memory 17 to create a record of the mismatch and non-verification. The subfile may include text information entered by the user with input device (e.g., a keyboard or key pad on display 157) indicating the nature of the resolution.

Decision point 326 is entered after block 325. If additional pouch package 23 subfiles of the batch file remain to be processed, the process loops to block 309 and packaging by the automatic drug packaging machine 11 continues. If the pouch package 23 subfile is the final subfile of the batch file at decision point 326, then the process proceeds to block 328.

At block 328 save log occurs and all data for the entire batch file is updated as saved in memory 17. The result of block 328 is that pouch packages 23 have either been verified as correct by code and image verification or any non-verified pouch packages have been corrected and the pouch packages are ready for administration. The process ends at 330.

Returning to decision points 333 and 337, the user determines that the displayed information matches. At decision point 337 the user confirms whether there is a mismatch after pausing the system 10 for the verification process of the pouch package 23 being verified as previously described.

At decision point 333 the user determines that the displayed information in block 331 is correct for the pouch package 23. For both decision points 333 and 337, the user may push match button 181, or the like, to indicate the information has been compared and is correct and to update the subfile for the pouch package 23. This affirmative action results in data generation for the pouch package 23 responsive to whether the comparison is a match. The data generation includes a verification of the pouch package based on the match.

As an alternative, the pharmacist or other user could simply take no action at decision point 333, with the default condition being a match for the pouch package 23. This non-action also results in data generation for the pouch package 23 responsive to whether the comparison is a match.

The pouch package 23 subfiles are preferably updated throughout the process on a package by package basis to generate data. And, after each subfile of the batch file is complete, the batch file is then updated and saved, for example at block 351. The data generation includes a verification of the pouch package 23 based on the match. The result of successful image comparison in decision points 333, 337 is that the pouch package is verified as correct and in compli-

ance with the prescription order. The pouch package 23 may subsequently be released for administration.

At decision point 345 a determination is made regarding whether the verified pouch package 23 is the final pouch package 23 of the batch file being verified. If there are other pouch packages 23 to be packaged as determined at decision point 345, the process loops to block 307 so that the next pouch package 23 can be packaged.

At block 351 save log occurs and all data for the entire batch file is updated as saved in memory 17. The result of block 328 is that pouch packages 23 have either been verified as correct by code and image verification or any non-verified pouch packages have been corrected and the pouch packages are ready for administration. The process ends at 352.

"Delayed Time" Verification

An exemplary delayed time image verification process will now be described in connection with FIG. 19B. The exemplary delayed time verification process provides the pharmacist or other user with the opportunity to package the pouch packages 23 at one time (for example, through completion of blocks 334 and 328 of FIG. 19A) and then to perform image review and verification of each pouch package 23 at any other time. By way of example, the delayed time verification process could occur one, two, or any number of days subsequent to output of the pouch packages 23 from automatic drug packaging machine 11 and completion of the first verification process based on the code comparison.

The second verification process may occur at workstation 153 as described in connection with the real time image verification mode. The workstation 153 can be at any location in data-transmission relationship with computer 15, or a like computer. All information for the delayed time verification may be in the subfile for each pouch package 23 saved during the first verification process. The pharmacist performs the review and verification using electronic records. There is no necessity that the pharmacist physically handle the pouch packages 23.

The process may be entered at Start 401. The pharmacist or user may login with biometrics or password login with access granted based on the user security level as previously described.

At block 403, the user first selects a batch or particular pouch packages for review and verification. The user may select a batch from a queue containing a plurality of batches awaiting image verification. The selection may be by any suitable manner including by touching a batch file displayed on touchscreen video display 157 or by scanning a code associated with the batch with a code-reader-type input device 159.

Selection of a batch accesses each subfile of the batch. The user may have the option to select for review the pouch packages based on any criterion such as: batch, patient, facility (e.g., hospital or long-term care facility, including by room, ward or other designation), by drug, or by pouch packages assigned to a medication cart or cabinet.

At block 405, and as with the real time verification, instructions executed by the computer 15 access a pouch package 23 subfile and present information to the user on the split screen touchscreen video display 157 at workstation 153.

At block 407, the information first presented to the user may be an indication of whether an error was detected during the first verification process ending at block 328 as indicated in the subfile for the pouch package 23. For example, a pouch package for which there was no code agreement could be identified to the user at block 407 for further attention, spe-

cifically to determine whether the pouch package **23** was properly packaged irrespective of the apparent code mismatch indicated at block **407**.

At block **409**, image information is presented to the user on display **157** to assist the user in understanding the source of the error indicated at decision point **407**. At block **409**, the instructions executed by computer **15** present generated data to the user on split screen touchscreen video display **157**, preferably in the same manner as for the real time verification in block **331** and as illustrated in FIG. **17**. The displayed information may include: the text information **167** and image information **169**, **171** of the pouch package first and second sides **67**, **69** from the subfile and reference image **173** of each drug **21** which should have been loaded in the pouch package **23**. The verification status **175** of display **157** would indicate non-verified.

At decision point **411**, the instructions executed by computer **15** provide for comparing of information generated at block **409** and a determination of whether the information matches. In the example, the instructions executed by computer **15** preferably provide for comparing at least the image **171** of the drugs within the pouch package **23** and a reference image **173** of each drug **21** which should have been loaded in the pouch package **23**.

At decision point **411**, the user examines the displayed information and compares the information indicating the expected content of the pouch package **23** and the information indicating what was actually packaged in the pouch package **23**. The user determines whether the information matches. An information match is indicative that the error indication at decision point **407** is false. If the information does not match, then steps must be taken to resolve the problem.

Block **413** is entered if the information does not match at decision point **411**. At block **413**, the user resolves the problem. Resolution involves any step necessary to provide all pouch packages **23** required by the prescription order. Resolution may be simply updating the status of the pouch package **23** to indicate that the pouch package is verified as correct. Resolution may involve re-generating the pouch package **23** for packaging by system **10** so that the prescription order is complete. Resolution may further involve removal of any non-verified and non-compliant pouch package **23** from the pouch package web **25**.

Block **415** is entered both if the result of decision point **411** is a match and after resolution of the problem in block **413**. The purpose of block **415** is to create a record of resolution of the non-verification at decision point **407** (i.e., a code mismatch). At block **415**, the pharmacist (indicated as "RPh" at block **415**) creates a record in the pouch package **23** subfile that the pouch package **23** is correct and verified and indicates any other resolution of the verification error at decision point **407**. Creation of such record in block **415** is desirable because the code mismatch at decision point **371** indicates that the pouch package **23** is non-verified and could contain a non-compliant drug **21**. The data may be generated by means of text entered with input device **159** or by selection of a resolution code from a menu available on display **157**.

At decision point **417**, if additional pouch package **23** subfiles of the batch file remain to be processed, the process loops to block **419**, the next subfile is accessed, and the process entered at decision point **407** is repeated until all pouch packages **23** of the batch have been verified or all problems resolved. If the pouch package subfile is the final subfile of the batch file at decision point **417**, then the process proceeds to block **421**.

Returning to decision point **407**, if the pouch package **23** was verified as correct in the first verification process as indicated in the subfile for the pouch package **23**, then the process moves to block **423**.

At block **423**, image information is presented to the user on display **157** so that the user can verify that the pouch package was packaged properly. At block **423**, the instructions executed by computer **15** present generated data to the user on split screen touchscreen video display **157** in the same manner as for the real time verification in block **331** and as illustrated in FIG. **17**. The displayed information **70** may include: the text information **167** and image information **169**, **171** of the pouch package first and second sides **67**, **69** from the subfile and reference image(s) **173** of each drug **21** which should have been loaded in the pouch package **23**.

At decision point **425**, the instructions executed by computer **15** provide for comparing of information generated at block **423** and a determination of whether the information matches. In the example, the instructions executed by computer **15** preferably provide for comparing at least the image **171** of the drugs within the pouch package **23** and a reference image **173** of each drug **21** which should have been loaded in the pouch package **23**.

At decision point **425**, the user examines the displayed information and compares the information indicating the expected content of the pouch package **23** and the information indicating what was actually packaged in the pouch package **23**. The user determines whether the information matches. If the information does not match, the pharmacist or other user may push the mismatch button **179** on touchscreen display **157** or otherwise operate a control to indicate the mismatch and non-verification. The process then continues to block **413** for problem resolution as previously described. It is further envisioned that a computer may recall and compare the aforementioned data elements to make the same determination of whether the displayed information matches. Such computer comparison could occur at workstation **153** or elsewhere.

If there is a match at decision point **425**, the user may push a match button **181** and the process continues to decision point **417**. This affirmative action of pushing the mismatch or match buttons **179**, **181** results in data generation for the pouch package **23** responsive to whether the comparison at decision point **425** is a match. The data generation includes a verification of the pouch package **23** based on the match and, alternatively, a non-verification of the pouch package **23** if there is not a match. The instructions executed by computer **15** may create a record of the pouch package verification or non-verification based on the result of the image comparison at decision point **423**. The record of the pouch package verification or non-verification is most preferably created in the subfile for the pouch package **23**, thereby creating information in database residing in memory **17** that can later be recalled to confirm the contents of each pouch package **23**. Absence of a mismatch record may be used to indicate that there was a match.

The delayed time verification process is repeated through decision point **417** until all subfiles in the batch file have been verified as correct, or otherwise resolved.

Block **421** is entered through decision point **417** for the final subfile of the batch. At block **421** save log occurs and all data for the entire batch file is updated as saved in memory **17**. All data for the batch file is now reviewed and verified by the pharmacist as correct or otherwise resolved in accordance with the prescription or other instructions. The process ends at **427**.

Optionally, in an embodiment, a user may elect to perform only the first verification process initiated at decision point

317 without use of image verification. In such an embodiment, the user may only utilize a code comparison initiated at decision point 317 to determine whether the pouch package is verified or non-verified.

In a further embodiment, the user may elect to perform only the second verification process initiated at block 331 or start 401 in which the image information displayed on the video display 157 is compared for a match. Such image verification may be in real time verification mode or may be in delayed time verification mode as described above.

The automatic drug packaging machine and package-less verification system 10 described herein provides a full and complete record of each pouch package 23 and the content of each pouch package 23. The record preferably indicates whether the codes match and whether the images match. In the example, a verification of the pouch package may be indicated in the record if the comparisons match so that the pouch package can be administered to the patient with confidence that the prescription order has been correctly fulfilled. Alternatively, a non-verification of the pouch package may be indicated if either of the comparisons do not result in a match. This permits the pharmacist to withhold the pouch package from the patient and to take corrective action.

The record may be accessed any time it is necessary to establish that each pouch package 23 was properly packaged. For example, if a patient or care giver asserts that there was an undercount or incorrect drug in a pouch package 23, the subfile for that pouch package 23 can be accessed to demonstrate that the pouch package 23 was properly packaged. Such record would be quite valuable, particularly because of the complex nature of tracking the content of the many pouch packages 23 output from the automatic drug packaging machine 11.

The system 10 improves patient care by ensuring that prescription orders are fulfilled correctly. And, the system 10 has the potential to control healthcare costs by making the verification more efficient and by freeing pharmacists to assist patients and perform other tasks.

Point of Care Image Verification

FIG. 20 illustrates that the saved information in each subfile has uses other than to perform registered pharmacist prescription order review and verification. FIG. 20 illustrates that the information saved in each subfile for each pouch package 23 can be utilized for point of care (identified as "POC" in FIG. 20) verification prior to administration of a drug to a patient.

The process of FIG. 20 begins after a prescription order has been reviewed and verified as correct by the processes described herein, and has been released for prescription order fulfillment by a pharmacist. The process of FIG. 20 may be executed through components in data-transmission relationship with the database residing in memory 17 of computer 15, or a like database storing information for each pouch package 23 subfile.

The process is entered at start 501.

At block 503 a care giver, such as a nurse at a point of care, prepares to administer drugs to a patient. The point of care may be a hospital, a long term care facility, or any other location at which drugs 21 are administered to a patient. The care giver obtains packaged drugs 21, which may be packaged in pouch packages 23 as illustrated in FIGS. 15A-16F. The pouch packages 23 may be unwound from a spool 147 delivered to the point of care or otherwise received from a pharmacy or other source.

At block 505, the care giver scans a machine-readable code 77 on a pouch package 23 with a code reader. The machine readable code 77 may be a barcode as illustrated in FIGS. 16A-16B and 16E-16F and the code reader may be a barcode reader. A video display, such as display 157 of FIG. 17, or other display device is provided at the point of care. The barcode reader and video display are in data-transmission relationship with the database storing the subfile information for the scanned pouch package 23.

At block 507, image information is presented to the care giver on display 157, or another display device, so that the care giver can further confirm that the pouch package 23 was packaged properly and is the proper drug 21 for the patient. At block 507, the instructions executed by computer 15, or a like device, present generated data to the care giver on split screen touchscreen video display 157 in the same manner as for the real time image verification in blocks 331, 409, and 423 of FIGS. 19A-19B and as illustrated in FIG. 17. The displayed information may include: the text information 167 and image information 169, 171 of the pouch package first and second sides 67, 69 from the subfile and reference image 173 of each drug 21 which should have been loaded in the pouch package 23.

At decision point 511, the care giver examines the displayed information and compares the information on the pouch package 23 in the care giver's possession and the information indicating what was actually packaged in the pouch package 23 as presented on the display. The care giver determines whether the information matches.

Block 513 is entered if the information does not match. If the information does not match, the care giver stops administration of the drug 21 and resolves the problem.

Block 515 represents an entry point for an optional verification process. At block 515, the care giver can scan a patient bar code worn, for example on the patient's wrist. The patient bar code may be entered into the subfile for each pouch package 23.

At decision point 517, the instructions executed by computer 15 determine whether the patient bar code matches the code in the subfile. A code match at decision point 517 indicates that the pouch package is properly matched to the patient.

At block 519, the care giver stops the administration process if the codes do not match. A code mismatch could indicate that the pouch package 23 is not intended for the patient.

Block 521 is entered if the information matches at decision point 511 or at optional decision point 517. In block 521, the care giver accepts the drug for administration to the patient. The acceptance may be implemented by pushing a button, such as match button 181, on video display 157. The acceptance causes the information in the subfile to be updated in the database residing on, for example, computer 15 creating a record of acceptance in the subfile.

At block 523, the drug is administered to the patient.

The process ends at 525 with a successful verification of the drug 21 prior to administration to the patient.

The process described herein creates a record of the drug 21 administered to the patient and a record of further verification that the correct drug 21 in accordance with the prescription order was administered to the patient. The record may be accessed at a future point in time to confirm the drug 21 administered to the patient.

Reference to a computer program product or computer executable instructions may take any form capable of generating a signal, causing a signal to be generated, or causing execution of a program of machine-readable instructions on a digital processing apparatus. A computer program product or

computer executable instructions may be embodied by a transmission line, a compact disk, digital-video disk, a magnetic tape, a Bernoulli drive, a magnetic disk, a punch card, flash memory, integrated circuits, or other digital processing apparatus memory device. Furthermore, the described features, structures, or characteristics of the invention may be combined in any suitable manner in one or more embodiments.

The steps shown in FIGS. **19**A, **19**B and **20** are described with respect to processes in the automatic drug packaging machine and drug verification system **10** of FIGS. **1-18**. It will be apparent to one of ordinary skill in the art, however, that the method steps shown in FIGS. **19**A-**19**B and **20**, are applicable to distributed systems having a variety of configurations. The method shown in FIGS. **19**A, **19**B and **20**, may also be performed by a process facilitating a service or performed by a separate process executed on a host, server or the like in a distributed system.

The apparatus, methods and computer code of the present invention may be performed by a computer program. The computer program can exist in a variety of forms both active and inactive. For example, the computer program can exist as software possessing program instructions or statements in source code, object code, executable code or other formats, firmware program(s), or hardware description language ("HDL") files. Any of the above can be embodied on a computer readable medium, which include storage devices and signals, in compressed or uncompressed form. Such computer readable storage devices include conventional computer RAM (random access memory), ROM (read only memory), EPROM (erasable, programmable ROM), EEPROM (electrically erasable, programmable ROM), magnetic or optical disks or tapes, firmware and similar storage modules. Computer readable signals, whether modulated using a carrier or not, can include heartbeat data packages, error data packages, test data packages and the like, all described above. It will be understood by those skilled in the art that a computer system hosting or running the computer program can be configured to access a variety of signals, including but not limited to signals downloaded through the Internet or other networks. Such may include distribution of executable software program(s) over a network, distribution of computer programs on a CD or DVD ROM, through firmware or through Internet download and the like.

The invention has been described with reference to preferred implementations thereof but it will be appreciated that variations and modifications within the scope of the invention will be suggested to those skilled in the art. For example, the invention may be implemented on networks including ethernet, token ring and the like or used to control other aspects of a system. The apparatus, methods and computer code of the present invention may be extended to monitor other devices which exhibit a plurality of operational modes.

Those skilled in the art will recognize that the techniques and embodiments described herein may be implemented with desirable results in all types of database systems. It is to be understood that several of the steps disclosed in the flow charts of FIGS. **19**A, **19**B and **20**, including but not limited to the adjustment of the circuit parameters or timing, could be performed by software, firmware or the like programmed to carry out such steps. These steps could be performed, by way of example only, through software, firmware or a program storage device which may be part of a digital computer or computer network. In accordance with the present invention, the program or storage device may be implemented by a processor within a computer that executes a series of computer-executable instructions. These instructions may reside,

for example, in RAM, ROM or other storage media of the computer, firmware or the like. Alternatively, the instructions may be contained on a data storage medium, such as a computer CD, DVD, ROM, RAM, diskette, USB drives, flash drive devices, solid state devices and the like. Furthermore, the instructions may be stored on a DASD array, magnetic tape, conventional hard disk drive, electronic read-only memory, flash memory, USB drives, optical storage device, solid state drives, or other appropriate data storage device. In such alternate embodiments, the computer-executable instructions may be lines of compiled executable code as available in any computer executable code, steps or language.

Reference throughout this specification to "the embodiment," "this embodiment," "the previous embodiment," "one embodiment," "an embodiment," "a preferred embodiment," "another preferred embodiment," or similar language means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases "in the embodiment," "in this embodiment," "in the previous embodiment," "in one embodiment," "in an embodiment," "in a preferred embodiment," "in another preferred embodiment," and similar language throughout this specification may, but do not necessarily, all refer to the same embodiment.

Furthermore, the described features, advantages, and characteristics of the invention may be combined in any suitable manner in one or more embodiments. One skilled in the relevant art will recognize that the invention may be practiced without one or more of the specific features or advantages of a particular embodiment. In other instances, additional features and advantages may be recognized in certain embodiments that may not be present in all embodiments of the invention.

While the present invention has been described in connection with certain exemplary or specific embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover various modifications, alternatives, modifications and equivalent arrangements as will be apparent to those skilled in the art. Any such changes, modifications, alternatives, equivalents and the like may be made without departing from the spirit and scope of the invention.

What is claimed is:

1. An automatic drug packaging machine and package-less verification system, comprising:
    an automatic drug packaging machine including a support structure, an information-application device and a packaging apparatus within the automatic drug packaging machine for packaging one or more drug into ones of separate pouch packages one after the other thereby forming a pouch package web, each pouch package having sides including a side through which each packaged drug is viewable;
    an imager secured with respect to the support structure to capture an image of the pouch package during formation of the pouch package web;
    a code reader secured with respect to the support structure to read a machine-readable code applied by the information-application device to each pouch package during formation of the pouch package web; and
    a computer programmed with instructions for performing a method of package-less verification of the pouch packages including:

storing information in non-volatile memory for packaging of each pouch package, the stored information including an identification code for each pouch package;

applying the stored information to a side of the pouch package with the information-application device during formation of the pouch package web, the applied information including human-readable information and a machine-readable code corresponding to the identification code;

packaging a drug within the pouch package during formation of the pouch package web;

capturing an image of the pouch package including each packaged drug therein and the applied human-readable information during formation of the pouch package web;

storing the image of the pouch package including the images of each packaged drug therein and the applied human-readable information with the stored information for the pouch package during formation of the pouch package web;

reading the machine-readable code with the code reader during formation of the pouch package web;

comparing the machine-readable code of the pouch package with the stored identification code for a match during formation of the pouch package web;

displaying the stored image of the pouch package including the images of each packaged drug therein and the applied human-readable information thereby enabling a comparison of the displayed images with the stored information for the pouch package for a match; and

creating a record for the pouch package during formation of the pouch package web responsive to whether the machine-readable code matches the stored identification code and creating a record for the pouch package responsive to whether the image of each packaged drug and the image of the applied human-readable information match the stored information for the pouch package, the pouch package being verified as correct if the comparisons match and, alternatively, being non-verified if at least one of the comparisons do not match.

2. The automatic drug packaging machine and packageless verification system of claim 1 wherein creating the record for the pouch package during formation of the pouch package web occurs automatically after reading the machine-readable code.

3. The automatic drug packaging machine and packageless verification system of claim 1 wherein the automatic drug packaging machine further comprises a module, the module includes the support structure, and the imager and code reader are secured to the support structure within the module.

4. The automatic drug packaging machine and packageless verification system of claim 3 wherein creating the record for the pouch package during formation of the pouch package web occurs before the pouch package exits the module.

5. The automatic drug packaging machine and packageless verification system of claim 3 wherein the module is capable of being secured to an automatic drug packaging machine housing.

6. The automatic drug packaging machine and packageless verification system of claim 1 wherein the method further includes creating a record of the pouch package verification or non-verification.

7. The automatic drug packaging machine and packageless verification system of claim 6 wherein creating the record

of the pouch package verification or non-verification further includes creating the record in a file for the pouch package.

8. The automatic drug packaging machine and packageless verification system of claim 1 wherein the method further includes generating an alarm if the codes do not match.

9. The automatic drug packaging machine and packageless verification system of claim 1 wherein the method further includes stopping the automatic drug packaging machine if the codes do not match.

10. The automatic drug packaging machine and packageless verification system of claim 1 wherein the method further includes providing a modification of the pouch package if the codes do not match.

11. The automatic drug packaging machine and packageless verification system of claim 10 wherein the modification provided is an identification mark made on the pouch package.

12. The automatic drug packaging machine and packageless verification system of claim 1 wherein the method further includes providing a classification code on the pouch package, the classification code including a color corresponding to the time of day at which each drug in the pouch package is to be taken by a patient.

13. The automatic drug packaging machine and packageless verification system of claim 1 wherein the method further includes providing a message package in the pouch package web proximate the pouch package, the message package including information relating to the pouch package.

14. The automatic drug packaging machine and packageless verification system of claim 1 wherein the applied information is on the side through which each packaged drug is viewable and the applied information and each packaged drug are viewable simultaneously.

15. The automatic drug packaging machine and packageless verification system of claim 1 wherein the machine-readable code of the pouch package is a barcode.

16. The automatic drug packaging machine and packageless verification system of claim 1 wherein the code reader is integrated with the imager.

17. The automatic drug packaging machine and packageless verification system of claim 1 further comprising a display and the comparison of the displayed images with the stored information occurs on the display.

18. The automatic drug packaging machine and packageless verification system of claim 17 including a first location at which the automatic drug packaging machine is located and the capturing of the image of the pouch package occurs and a second location different from and spaced from the first location at which the display is located and at which the comparison occurs.

19. The automatic drug packaging machine and packageless verification system of claim 17 wherein the applied human-readable information is on a pouch package first side, the side through which each packaged drug is viewable is a pouch package second side, and the imager further includes:

a first imaging device secured with respect to the support structure adjacent the pouch package web to capture an image of the applied information on the pouch package first side; and

a second imaging device secured with respect to the support structure adjacent the pouch package web to capture the image of the pouch package second side and each packaged drug viewable through the second side.

20. The automatic drug packaging machine and packageless verification system of claim 19 wherein the method further includes:

capturing an image of the applied information on the pouch package first side with the first imaging device;

capturing an image of the pouch package second side through which each packaged drug is viewable with the second imaging device; and

the comparison of the images of the pouch package first side, the pouch package second side and the stored information for the pouch package occurs on the display.

21. The automatic drug packaging machine and package-less verification system of claim **20** wherein the method further includes associating an image of the pouch package first side and an image of the pouch package second side with a file for the pouch package.

22. The automatic drug packaging machine and package-less verification system of claim **21** wherein the method further includes creating a record in the file that the pouch package has been verified as correct by a user.

23. The automatic drug packaging machine and package-less verification system of claim **1** wherein the pouch package further includes a side in addition to the side through which each packaged drug is viewable, the information-application device comprises a printer, and the method further includes printing the applied information on a side.

24. The automatic drug packaging machine and package-less verification system of claim **23** wherein the applied information includes a registration mark detectable by the imager and the method further includes capturing the image of the

pouch package side including the applied information responsive to detection of the registration mark.

25. The automatic drug packaging machine and package-less verification system of claim **24** wherein the method further includes:

selecting a size for the pouch package from a plurality of different sizes; and

printing the applied information including the registration mark on a pouch package side at a position based on the selected pouch package size so that the applied information is in position for imaging by the imager.

26. The automatic drug packaging machine and package-less verification system of claim **1** wherein the automatic drug packaging machine further comprises:

a cassette;

a first counter associated with the cassette, the counter making a count when each drug is dispensed from the cassette;

a second counter associated with the packaging apparatus which receives each drug dispensed from the cassette, the second counter making a count when each drug is loaded into the pouch package web for forming a pouch package; and, wherein,

the method further includes comparing the counts with an expected count for the pouch package to confirm that the expected count was packaged in the pouch package.

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